Pharma Code
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FRONT SI

Slinda

Drospirenone

film-coated tablets 4 mg

Exeltis
Rethinking healthcare

1.NAME OF THE MEDICINAL PRODUCT

Slinda 4 mg film-coated tablets

2.QUALITATIVE AND QUANTITATIVE COMPOSITION

White active film-coated tablets: Each tablet contains 4 mg of drospirenone.
Green placebo film-coated tablets: The tablet does not contain active substances.
Excipient with known effect:
Each white active film-coated tablet contains 17.5 mg of lactose.
Each green placebo film-coated tablet contains 52.7 mg of lactose (as monohydrate), equivalent to 55.5 mg of lactose monohydrate. For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet (tablet).
The active tablet is a round, white tablet with the letters “E” and “D” debossed on opposite sides, with a diameter of 5 mm.
The placebo tablet is a round, green tablet with the letter “E” and the number “4” debossed on opposite sides, with a diameter of 5 mm.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Contraception

4.2 Posology and method of administration

Posology

How to take Slinda

One tablet is to be taken daily for 28 consecutive days, one white active tablet daily during the first 24 days and one green inactive tablet daily during the 4 following days. Tablets must be taken every day at about the same time of the day so that the interval between two tablets is always 24 hours. Tablets should be taken in the order shown on the blister. Stickers marked with the 7 days of the week are provided. The woman should choose the sticker that starts with the day she begins taking the tablets and stick it on the blister. The first tablet of the treatment should be taken on the first day of menstrual bleeding. There after tablet taking is continuous. A subsequent pack is started immediately after finishing the previous pack, without a break in daily tablet intake.

How to start Slinda

No preceding hormonal contraceptive use (in the past month)

Tablet-taking has to start on day 1 of the woman's natural cycle (first day of her menstrual bleeding). When doing so, no additional contraceptive measures are necessary.

Following first-trimester abortion

After first-trimester abortion it is recommended to start Slinda immediately after abortion took place. In that case there is no need to use an additional contraceptive method.

Following delivery or second-trimester abortion

Contraceptive treatment with Slinda is recommended to start between 21 and 28 days after delivery or second trimester abortion. If contraceptive treatment with Slinda is initiated later but before the menstruations have returned, pregnancy must be ruled out and an additional method of contraception should be used for the first week.

For breast-feeding women, see section “Fertility, pregnancy and lactation”.

Changing from a combined hormonal contraceptive (combined oral contraceptive (COC), vaginal ring or transdermal patch)

The woman should start Slinda preferably on the day after the last active tablet (the last tablet containing the active substances) of her previous COC or on the day of removal of her vaginal ring or transdermal patch. In these cases, the use of an additional contraceptive is not necessary. The woman may also start Slinda at the latest on the day following the usual tablet-free, ringfree, patch free or placebo tablet interval of her previous combined hormonal contraceptive, but during the first 7 days of tablet taking an additional barrier method is recommended.

Changing from a progestogen-only-method (progestogen-only pill (POP), injection, implant) or from a progestogen-releasing intrauterine system (IUS)

The woman may switch any day from another POP and should start Slinda the day after, within 24 hours of discontinuing the previous POP. A woman may switch from an implant or following IUS removal on the same day that the implant or IUS is removed. A woman may switch from using an injectable contraceptive and should start Slinda on the day the next injection was due to occur. In all of these cases, the use of an additional contraceptive is not necessary.

Management of missed tablets

Management of missed tablets

Tablets should be taken every 24 hours. If the women is less than 24 hours late in taking any single tablet, contraceptive protection is not reduced. The woman should take the tablet as soon as she remembers and should take further tablets at the usual time.

If the user is more than 24 hours late in taking any white active tablet, contraceptive protection may be reduced and use of a barrier method such as a condom should be considered for the next 7 days. The missed tablet should be taken as soon as it is remembered, even if this means taking two tablets at the same time. She then continues to take tablets at her usual time.

If tablets were missed in the first week after initiation of Slinda and intercourse took place in the week before the tablets were missed, the possibility of a pregnancy should be considered.

If tablets were missed in the third week of pill taking, the risk of reduced reliability is imminent because of the forthcoming 4-day hormone-free interval. However, by adjusting the tablet intake schedule, reduced contraceptive protection can still be prevented. The user should take the last missed tablet as soon as she remembers, even if this means taking two tablets at the same time. She then continues to take the active tablets at her usual time. The user is advised not to take the placebo pills and continue straight on to the next active blister pack.

Missed (green) placebo tablets can be disregarded. However, they should be discarded to avoid unintentionally prolonging the interval between active tablet taking.

Advice in case of gastrointestinal disturbances

In case of severe gastrointestinal disturbances (e.g., vomiting or diarrhea), absorption may not be complete and additional contraceptive measures should be taken.

If vomiting or diarrhea occurs within 3-4 hours after tablet taking, a new (replacement) tablet should be taken as soon as possible. The new tablet should be taken within 24 hours of the usual time of tablet-taking if possible. If more than 24 hours elapse, the advice concerning missed tablets, as given in section 4.2 "Management of missed tablets", is applicable. If the woman does not want to change her normal tablet-taking schedule, she has to take the extra tablet(s) from another blister pack.

Paediatric population

Safety and efficacy of Slinda have been established in women of reproductive age. Safety and efficacy are expected to be the same for post pubertal adolescents under the age of 18 and users 18 years and older. Use of this product before menarche is not indicated.

Method of administration: Oral use.

4.3 Contraindications

Progestogen-only contraceptives (POCs) like Slinda should not be used in the presence of any of the conditions listed below. Should any of the conditions appear for the first time during Slinda use, the medicinal product should be discontinued immediately.

- Active venous thromboembolic disorder.
- Presence or history of severe hepatic disease as long as liver function values have not returned to normal.
- Severe renal insufficiency or acute renal failure.
- Known or suspected sex-steroid sensitive malignancies.
- Undiagnosed vaginal bleeding.
- Hypersensitivity to the active substance or to any of the excipients listed in section "List of excipients".

4.4 Special warnings and precautions for use

If any of the conditions/risk factors mentioned below is present, the benefits of Slinda should be weighed against the possible risks for each individual woman and discussed with the woman before she decides to start using Slinda. In the event of aggravation, exacerbation or first appearance of any of these conditions, the woman should contact her physician. The physician should then decide whether Slinda use should be discontinued.

Hyperkalemia

Drospirenone is an aldosterone antagonist with potassium sparing properties. In most cases, no increase of potassium levels is to be expected. However, it is recommended to check serum potassium levels during the first treatment cycle in women presenting with renal insufficiency and pre-treatment serum potassium in the upper reference range and during concomitant use of potassium sparing medicinal products (see section "Interaction with other medicinal products and other forms of interaction").

Circulatory disorders

From epidemiological studies there is little evidence for an association between progestogen only preparations and an increased risk of myocardial infarction or cerebral thromboembolism. Rather, the risk of cardiovascular and cerebral events is related to increasing age, hypertension, and smoking. In women with hypertension the risk of stroke may be slightly enhanced by progestogen-only preparations.

Although not statistically significant, some studies indicate that there may be a slightly increased risk of venous thromboembolism (deep venous thrombosis, pulmonary embolism) associated with the use of progestogen-only preparations. Generally recognized risk factors for venous thromboembolism (VTE) include a positive personal or family history (VTE in a sibling or a parent at a relatively early age), age, obesity, prolonged immobilization, major surgery or major trauma. Treatment should be stopped at once if there are symptoms of an arterial or venous thrombotic event or suspicion thereof and discontinuation of Slinda should be considered in case of rolonged immobilization due to surgery or illness.

Bone metabolism

Treatment with Slinda leads to decreased estradiol serum levels, to a level corresponding with the early follicular phase. It is currently unknown whether the decrease in estradiol serum levels may have a clinically relevant effect on bone mineral density. Loss of bone mineral density is of particular concern during adolescence and early adulthood, a critical period of bone accretion. It is unknown if bone mineral density decrease in this population will reduce peak bone mass and increase the risk for fracture in later life.

Breast Cancer

Breast Cancer

A meta-analysis from 54 epidemiological studies reported that there is a slightly increased relative risk (RR = 1.24) of having breast cancer diagnosed in women who are currently using oral contraceptives (OCs), mainly using estrogen-progestogen preparations. The excess risk gradually disappears during the course of the 10 years after cessation of combined OC (COC) use.

Because breast cancer is rare in women under 40 years of age, the excess number of breast cancer diagnoses in current and recent COC users is small in relation to the overall risk of breast cancer.

These studies do not provide evidence for causation. The observed pattern of increased risk may be due to an earlier diagnosis of breast cancer in OC users, the biological effects of OCs or a combination of both. The breast cancers diagnosed in users of OCs tend to be less advanced clinically than the cancers diagnosed in those who have never used OCs.

The risk of having breast cancer diagnosed in users of progestogen-only preparations is possibly of similar magnitude to that associated with COC. However, for progestogen-only preparations, the evidence is based on much smaller populations of users and so is less conclusive than that for COCs.

Other tumours

In rare cases, benign liver tumours, and even more rarely, malignant liver tumours have been reported in users of combined hormonal contraceptives. In isolated cases, these tumours have led to life threatening intra-abdominal haemorrhages. A hepatic tumour should be considered in the differential diagnosis when severe upper abdominal pain, liver enlargement or signs of intra-abdominal haemorrhage occur.

Ectopic pregnancy

The protection with traditional progestogen-only pills against ectopic pregnancies is not as good as with combined oral contraceptives, which has been associated with the frequent occurrence of ovulations during the use of progestogen-only pills. Despite the fact that Slinda consistently inhibits ovulation ectopic pregnancy should be taken into account in the differential diagnosis if the woman presents amenorrhoea or abdominal pain.

Liver function

Discontinue Slinda if jaundice develops. Steroid hormones may be poorly metabolized in patients with impaired liver function. Acute or chronic disturbances of liver function may require the discontinuation of Slinda use until markers of liver function return to normal and Slinda causation has been excluded.

Diabetes

Although progestogens may have an effect on peripheral insulin resistance and glucose tolerance, there is no evidence for a need to alter the therapeutic regimen in diabetics using POPs such as Slinda. However, diabetic patients should be carefully observed during the first months of use. Special attention should be paid to diabetic patients with vascular involvement.

Other conditions

If a sustained hypertension develops during the use of Slinda or if a significant increase in blood pressure does not adequately respond to antihypertensive therapy, the discontinuation of Slinda should be considered.

Like with any other hormonal contraceptive, chloasma may occasionally occur, especially in women with a history of chloasma gravidarum. Women with a tendency to chloasma should avoid exposure to the sun or ultraviolet radiation whilst taking Slinda.

Depressed mood and depression are well-known undesirable effects of hormonal contraceptive use (see section "Undesirable effects"). Depression can be serious and is a well-known risk factor for suicidal behaviour and suicide. Women should be advised to contact their physician in case of mood changes and depressive symptoms, appearing shortly after initiation of the treatment.

The following conditions have been reported both during pregnancy and during sex steroid use, but an association with the use of progestogens has not been established: jaundice and/or pruritus related to cholestasis; gallstone formation; porphyria; systemic lupus erythematosus; haemolytic uraemic syndrome; Sydenham's chorea; herpes gestationis; otosclerosis-related hearing loss; (hereditary) angioedema.

Each white active tablet contains 17.50 mg of lactose and each green placebo tablet contains 52.7 mg of lactose (as monohydrate). Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Medical examination/consultation

Prior to the initiation or reinstitution of Slinda a complete medical history (including family history) should be taken and pregnancy must be ruled out. Blood pressure should be measured, and a physical examination should be performed, guided by the contra-indications (see section "Contraindications") and warnings (see section "Special warnings and precautions for use"). The woman should also be instructed to carefully read the user leaflet and to adhere to the advice given. The frequency and nature of examinations should be based on established practice guidelines and be adapted to the individual woman.

Women should be advised that oral contraceptives do not protect against HIV infections (AIDS) and other sexually transmitted diseases.

Changes in the menstrual bleeding pattern

Disruption of the menstrual bleeding pattern may occur during use of hormonal contraceptives that inhibit ovulation, including Slinda (see section "Pharmacodynamic properties").

If the bleeding is very frequent and irregular, another contraceptive method should be considered. If the symptoms persist, an organic cause should be ruled out. Management of amenorrhoea during treatment depends on whether or not the tablets have been taken in accordance with the instructions and may include a pregnancy test. The treatment should be stopped if a pregnancy occurs.

Reduced efficacy

pregnancy test. The treatment should be stopped if a pregnancy occurs.

Reduced efficacy

The efficacy of POPs may be reduced in the event of e.g. missed tablets (see section "Posology and method of administration"), gastro-intestinal disturbances (see section "Posology and method of administration") or concomitant medication (see section "Interaction with other medicinal products and other forms of interaction").

Laboratory tests

The use of contraceptive steroids may influence the results of certain laboratory tests, including biochemical parameters of liver, thyroid, adrenal and renal function, serum levels of (carrier) proteins, e.g. corticosteroid binding globulin and lipid/lipoprotein fractions, parameters of carbohydrate metabolism and parameters of coagulation and fibrinolysis.

4.5 Interaction with other medicinal products and other forms of interaction

Influence of other medicinal products on Slinda

Interactions can occur between Slinda and other medicinal products that induce microsomal enzymes. This can result in increased clearance of sex hormones and may lead to breakthrough bleeding and/or contraceptive failure.

Management

Enzyme induction can already be observed after a few days of treatment. Maximum enzyme induction is generally seen within a few weeks. After drug therapy is discontinued, enzyme induction may be sustained for about 4 weeks.

Short-term treatment

Women on treatment with enzyme inducing drugs should temporarily use a barrier method or another method of contraception in addition to the POP. The barrier method must be used during the whole time of the concomitant drug therapy and for 28 days after its discontinuation. If the drug therapy runs beyond the end of the active tablets in the POP pack, the placebo tablets must be discarded, and the next POP pack should be started right away.

Long-term treatment

In women on long-term treatment with enzyme-inducing active substances, another reliable, nonhormonal, method of contraception is recommended. The following interactions have been reported in the literature (mainly with combined contraceptives but occasionally also with progestogen-only pills).

Substances increasing the clearance of contraceptive hormones (diminished contraceptive efficacy by enzyme induction) e.g.: Barbiturates, bosentan, carbamazepine, phenytoin, primidone, rifampicin, and HIV medication ritonavir, nevirapine and efavirenz and possibly also felbamate, griseofulvin, oxcarbazepine, topiramate and products containing the herbal remedy St. John's Wort (hypericum perforatum).

Substances with variable effects on the clearance of contraceptive hormones:

When co-administered with sex hormones, many combinations of HIV protease inhibitors (e.g. ritonavir, nelfinavir) and non-nucleoside reverse transcriptase inhibitors (e.g. nevirapine, efavirenz) and/or combinations with Hepatitis C virus (HCV) medicinal products (e.g. boceprevir, telaprevir), can increase or decrease plasma concentrations of progestins. The net effect of these changes may be clinically relevant in some cases.

Therefore, the prescribing information of concomitant HIV/HCV medications should be consulted to identify potential interactions and any related recommendations. In case of any doubt, an additional barrier contraceptive method should be used by women on protease inhibitor or non-nucleoside reverse transcriptase inhibitor therapy.

Substances decreasing the clearance of contraceptive hormones (enzyme inhibitors):

The clinical relevance of potential interactions with enzyme inhibitors remains unknown. Concomitant administration of strong or moderate CYP3A4 inhibitors such as azole antifungals (e.g. fluconazole, itraconazole, ketoconazole, voriconazole), verapamil, macrolides (e.g. clarithromycin, erythromycin), diltiazem and grapefruit juice can increase plasma concentrations of the progestogen.

In a multiple dose study evaluating the daily (10 days) co-administration of the strong CYP3A4 inhibitor ketoconazole with two drospirenone-containing hormone preparations (drospirenone 3 mg + estradiol 1.5 mg and drospirenone 3 mg + ethinylestradiol 0.02 mg) the AUC (0-24h) of drospirenone was increased 2.3-fold and 2.7-fold, respectively.

Influence of Slinda on other medicinal products

Hormonal contraceptives may affect the metabolism of certain other active substances. Accordingly, plasma and tissue concentrations may either increase (e.g. cyclosporine) or decrease (e.g. lamotrigine).

Based on in vitro studies and in vivo interaction studies in female volunteers using omeprazole, simvastatin and midazolam as marker substrate, a clinically relevant interaction of drospirenone with the cytochrome P450 mediated metabolism of other active substances is unlikely.

Pharmacodynamic interactions

Published data did not show a significant effect on serum potassium following the concomitant use of drospirenone and ACE-inhibitors or NSAIDs in patients without renal insufficiency. The concomitant use of Slinda with aldosterone antagonists or potassium-sparing diuretics has not been studied. In this case, serum potassium should be tested during the first treatment cycle (see section "Special warnings and precautions for use").

4.6 Fertility, pregnancy and lactation

Pregnancy

4.6 Fertility, pregnancy and lactation

Pregnancy

Slinda should not be used during pregnancy.

If pregnancy occurs during treatment with Slinda, further intake should be stopped.

Epidemiological studies have revealed neither an increased risk of birth defects in children born to women who used drospirenone prior to pregnancy, nor a teratogenic effect when drospirenone was taken inadvertently during pregnancy.

Animal studies have shown reproductive toxicity (see section "Preclinical safety data") Based on these animal data, undesirable effects due to hormonal action of the active compound cannot be excluded.

Breastfeeding

Negligible amounts of drospirenone are excreted in the breast milk. The daily dose of drospirenone in the baby is <1% of the maternal dose. Thus, at therapeutic doses of Slinda, no effects on the breastfed newborns/infants are anticipated. Based on the available data Slinda may be used during lactation.

Fertility

Slinda is indicated for the prevention of pregnancy.

EVERSO

4.7 Effects on ability to drive and use machines

No studies on the influence on the ability to drive and use machines have been performed with Slinda.

No effects on ability to drive and use machines have been observed in users of oral hormonal contraceptives.

4.8 Undesirable effects

Changes in the bleeding pattern was an adverse reaction frequently reported in the clinical trials (see section "Pharmacodynamic properties"). The most commonly reported adverse reactions in long-term clinical trials of more than 9 cycles of treatment with <drospirenone> (2,700 women) were acne (3.8%), metrorrhagia (2.9%), headache (2.7%) and breast pain (2.2%).

Tabulated list of adverse reactions

Adverse reactions that have been reported in short- and long- term clinical trials with Slinda are listed in the table below. All adverse reactions are listed by system organ class and frequency: very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000).

System Organ Class (MedDRA version 17.1)	Common	Uncommon	Rare
Infections and infestations		Vaginal infection	
Neoplasms benign. malignant and unspecified		Uterine leiomyoma	
Blood and lymphatic system disorders		Anaemia	
Immune system disorders		Hypersensitivity	
Metabolism and nutrition disorders		Appetite disorder Hyperkalaemia	
Psychiatric disorders	Libido disorder Mood disturbances	Anxiety symptoms Depression Depressed mood	
Nervous system disorders	Headache	Dizziness	
Eye disorders			Contact lens intolerance
Vascular disorders		Hot flush Hypertension	
Gastrointestinal disorders	Nausea Abdominal pain	Vomiting Diarrhoea Constipation	
Skin and subcutaneous tissue disorders	Acne	Alopecia Hyperhidrosis Rash Seborrhoea Pruritus Dermatitis	
Renal and urinary disorders			Polyuria

		Dermatitis	
Renal and urinary disorders			Polyuria
Reproductive system and breast disorders	Breast discomfort Metrorrhagia Vaginal haemorrhage Dysmenorrhea Menstruation irregular	Amenorrhoea Menstrual disorders Pelvic pain Ovarian cyst Vulvovaginal dryness Vaginal discharge	Breast cyst Cervical dysplasia Galactorrohoea Vulvovaginal pruritus
General disorders and administration site condition		Fatigue Oedema peripheral	
Investigations	Weight increased	Transaminases increased Blood bilirubin increased Blood creatine phosphokinase increased GammaGlutamyltransferase increased Blood triglycerides increased	Weight decreased

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V: *https://www.ema.europa.eu/docs/en_GB/document_library/Template_or_form/2013/03/WC500139752.doc* or to our Pharmacovigilance Department (email: pv.indonesia@exeltis.com ; Phone: +62-822-2517-7979) or report to Pharmacovigilance Center/ MESO National DITWAS KMEI ONAPPZA BPOM (email: pv-center@pom.go.id ; Phone: +62-21-4244691 Ext. 1079 ; Website: https://e-meso.pom.go.id/ADR).

4.9 Overdose

There have been no reports of serious deleterious effects from overdose. Symptoms that may occur in this case are nausea, vomiting and slight vaginal bleeding. There are no antidotes and further treatment should be symptomatic.

Drospirenone however is a spironolactone analogue which has antimineralocorticoid properties. Serum potassium and sodium, and evidence of metabolic acidosis, should be monitored in cases of overdose.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Hormonal contraceptives for systemic use, progestogens ATC code: G03AC10

Mechanism of action

Slinda is a progestogen-only-pill which contains the progestogen drospirenone, derived from spironolactone.

In a therapeutic dosage, drospirenone also possesses antiandrogenic and mild antimineralocorticoid properties. It has no estrogenic, glucocorticoid and antiglucocorticoid activity. This gives drospirenone a pharmacological profile closely resembling the natural hormone progesterone.

There are indications from clinical studies that for combined hormonal contraceptives containing 3 mg drospirenone and 0.02 mg ethinylestradiol, the mild antimineralocorticoid properties result in a mild antimineralocorticoid effect.

Pharmacodynamic effects

The contraceptive effect of Slinda is achieved primarily by inhibition of ovulation. Drospirenone exhibits a strong anti-gonadotropic activity inhibiting follicular stimulation and ovulation by suppression of the luteinising hormone (LH). In addition, drospirenone has an effect on the cervix increasing the viscosity of the cervical mucus. Drospirenone also exerts progestational effects on the endometrium, which becomes thinner.

Clinical efficacy and safety

The ovulation inhibition potential of Slinda (drospirenone 4 mg non-micronized administered daily for 24 days) as reflected by the ovarian activity [follicular growth, endogenous estradiol and progesterone serum concentrations (Hoogland score)] in comparison to 0.075 mg of desogestrel administered daily for 28 days over two treatment cycles was assessed in a randomized, open-label Phase II study conducted in 60 healthy young women. In cycle 1, no ovulation was observed in either treatment, whereas one ovulation was observed for Slinda and one for 0.075 mg of desogestrel group in cycle 2.

In a Phase II study performed in 130 women, Slinda maintained the inhibition of ovulation in spite of four fixed scheduled delayed intakes of 24 hours each on day 3, 6, 11 and 22.

In two multicenter Phase III European clinical trials, one single-arm study and one controlled study vs. desogestrel 0.075 mg, 1596 women have been treated for 9 up to 13 consecutive cycles with Slinda and 341 with desogestrel for 9 months. In the pooled analysis of these two studies the following Pearl Indexes were calculated:

Pearl Index (18-45 years of age), user + method failure: 0.73 (upper limit 95% confidence interval 1.43)

Pearl Index (18-35 years of age), user + method failure: 0.93 (upper limit 95% confidence interval 1.84)

Pearl Index (18-35 years of age), user + method failure: 0.93 (upper limit 95% confidence interval 1.84)
In a single arm multicenter Phase III clinical trial performed in 39 US sites, the efficacy population consisted of 953 females ≤ 35 years of age with 5,547 evaluable cycles. During these cycles, 17 (1.8 %) pregnancies were reported (irrespectively of confirmation by urine and serum pregnancy tests at the study site) leading to a Pearl Index (95% CI) of 4.0 (2.3, 6.4).

Bleeding pattern

The bleeding pattern during use of Slinda was assessed in a 9-month comparative, double blind trial vs desogestrel 0.075 mg, used continuously.
The occurrence of a withdrawal bleeding (defined as a bleeding starting during the 4 hormonefree days of Slinda lasting for up to 8 consecutive days), was highest – occurring in less than 40% - during the first cycles and decreased with time. After 9 months of use, a withdrawalbleeding was recorded in less than 20% of users.
The mean number of bleeding/spotting days in the Slinda group vs the desogestrel group during the cycles 2-4 was 13.1 ± 13.0 vs 16.9 ± 16.9, respectively. The mean number of bleeding/spotting days during cycles 7-9, was 9.7 ± 10.4 vs 10.8 ± 13.3, respectively.
In the same study, the proportion of subjects without any bleeding/spotting (amenorrhea) during cycles 2-4 was 20,1% for Slinda and 13,5% for desogestrel. The proportion of subjects with amenorrhea increased in cycles 7-9 to 26,7% for Slinda and to 32,1% in the desogestrel group.
The number of subjects with prolonged bleeding (>10 consecutive days) for Slinda vs desogestrel was 18,1% and 26,1 %, respectively, during cycles 2-4 and 9,1% and 16,7%, respectively, during cycles 7-9.
The rate of subjects who withdrew from the study due to bleeding related adverse events was 3.3 % in the Slinda group and 6.6 % in the desogestrel group.

Paediatric population

A phase III study was conducted in Europe to evaluate tolerability, safety and acceptability of Slinda. 103 adolescents were included in a 6-cycle core part and 7 additional cycles (extension phase) for a total of 13 cycles, Slinda was well tolerated and accepted by the subjects.
Bleeding pattern with Slinda was assessed and data were generally consistent with those from the Phase 3 studies in adults. Slinda was associated with a decrease in the percentage of subjects experiencing bleeding or spotting over time.

5.2 Pharmacokinetic properties

Absorption

Orally administered drospirenone is rapidly and almost completely absorbed. Maximum concentrations of Slinda active substance in plasma of about 28 ng/ml are reached at about 3-4 h after single ingestion. Concomitant ingestion of food has no influence on the extent of absorption of drospirenone.
The pharmacokinetics of Slinda after single and repeated dose has been studied in comparison with the marketed product containing 3 mg of micronized drospirenone in combination with ethinyl estradiol. After multiple dose administration, the relative bioavailability of Slinda was 76.51 % for AUCt.ss. The accumulation ratio expressed by Rac (AUC) was 1.9256 while it was 2.7684 for the combined product. These findings indicate that the total exposure to drospirenone is lower for Slinda than for the combined product on the market in a cycle of 28 days.

Distribution

Drospirenone is 95 % to 97 % bound to serum albumin and does not bind to sex hormone binding globulin (SHBG) or corticosteroid binding globulin (CBG). The mean apparent volume of distribution of drospirenone is approximately 4 l/kg.

Biotransformation

Drospirenone is extensively metabolized after oral administration. Two major non-pharmacologically active metabolites in the plasma are the acid form of drospirenone, generated by opening of the lactone ring, and the 4,5-dihydro-drospirenone-3-sulfate, both of which are formed without involvement of the P450 system. Drospirenone is also subject to oxidative metabolism catalysed by CYP3A4.
In vitro, drospirenone is capable to inhibit weakly to moderately the cytochrome P450 enzymes CYP1A1, CYP2C9, CYP2C19 and CYP3A4.

Elimination

After oral administration, plasma drospirenone levels decrease with a terminal half-life of 32 h. The metabolic clearance rate of drospirenone in serum is 1.5 ± 0.2 ml/min/kg. Drospirenone is excreted only in trace amounts in unchanged form. The metabolites of drospirenone are excreted with the faeces and urine at an excretion ratio of about 1.2 to 1.4.

Linearity/non-linearity

The pharmacokinetics of oral drospirenone is dose proportional following single doses ranging from 1-10mg.

Steady-state conditions

During a treatment cycle, maximum steady-state concentrations of drospirenone in serum of about 40 ng/ml are reached after about 7 days of treatment. Plasma drospirenone levels accumulate by a factor of about 2 as a consequence of the ratio of terminal half-life and dosing interval.

Special populations

Effect of renal impairment

No studies have been conducted to evaluate the effect of renal impairment on the pharmacokinetics of Slinda.

Special populations
Effect of renal impairment
No studies have been conducted to evaluate the effect of renal impairment on the pharmacokinetics of Slinda. However, steady-state serum drospirenone levels in women under treatment with a COC containing drospirenone with mild renal impairment (creatinine clearance CLcr, 50-80 mL/min) were comparable to those of women with normal renal function. The serum drospirenone levels were on average 37% higher in women with moderate renal impairment (CLcr, 30 - 50 mL/min) compared to those in women with normal renal function. Drospirenone treatment was also well tolerated by women with mild and moderate renal impairment. Drospirenone treatment did not show any clinically significant effect on serum potassium concentration.
Effect of hepatic impairment
No studies have been conducted to evaluate the effect of hepatic disease on the pharmacokinetics of Slinda. However, steroid hormones may be poorly metabolized in women with impaired liver function.
In a single dose study in women taking a COC containing drospirenone, oral clearance (CL/F) was decreased approximately 50 % in volunteers with moderate hepatic impairment as compared to those with normal liver function. The observed decline in drospirenone clearance in volunteers with moderate hepatic impairment did not translate into any apparent difference in terms of serum potassium concentrations. Even in the presence of diabetes and concomitant treatment with spironolactone (two factors that can predispose a patient to hyperkalemia) an increase in serum potassium concentrations above the upper limit of the normal range was not observed. It can be concluded that drospirenone is well tolerated in patients with mild or moderate hepatic impairment (Child-Pugh B).
Ethnic groups
No clinically relevant differences in the pharmacokinetics of drospirenone between Japanese and Caucasian women have been observed.

5.3 Preclinical safety data

In laboratory animals, the effects of drospirenone were confined to those associated with the recognised pharmacological action. In particular, reproduction toxicity studies revealed embryotoxic and fetotoxic effects in animals which are considered as species specific. At exposures exceeding those in users of drospirenone, effects on sexual differentiation were observed in rat fetuses but not in monkeys.
Environmental risk assessment studies have shown that drospirenone may pose a risk for the aquatic environment as reproductive effects in fish were evident at 0.087 ug/L (the LOEC). (See section “Special precautions for disposal”).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White active film-coated tablets:
Tablet core: Microcrystalline cellulose; Lactose; Silica, colloidal (E551); Magnesium stearate (E470b)
Tablet coat: Poly(vinyl alcohol); Titanium dioxide (E171); Macrogol; Talc (E553b);
Green placebo film-coated tablets:
Tablet core: Lactose monohydrate; Maize starch; Povidone; Silica, colloidal (E551); Magnesium stearate (E470b)
Tablet coat: Hypromellose (E464); Triacetin; Polysorbate 80 (E433); Titanium dioxide (E171); Indigo carmine aluminium lake (E132); Yellow Iron Oxide (E172)

6.2 Incompatibilities

Not applicable.6.3

6.3 Special precautions for storage

Store below 30ºC

6.4 Nature and contents of container

Transparent PVC-PVDC/Aluminium blister containing 28 film-coated tablets (24 white active film-coated tablets and 4 green placebo film-coated tablets).
Pack sizes: calendar-packs containing 1x28 film-coated tablets.
In addition to the carton box, a carton case for the blister is enclosed.

6.5 Special precautions for disposal

This medicinal product may pose a risk to the environment. (See section “Preclinical safety data”).
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

6.6 Pack size

Box, 1 Blisters @ 24 Film-coated tablets (active) + 4 Film-coated tablets (Placebo)
Reg No. DKI2138100617A1

HARUS DENGAN RESEP DOKTER

Manufactured by:
Laboratorios Leon Farma, S.A.,
Navatejera, Spain
Imported by:
PT. Nufarindo,
Semarang, Indonesia

Slinda
Drospirenone
tablet salut selaput 4 mg

Exeltis
Rethinking healthcare

LEAFLET: INFORMASI UNTUK PENGGUNA

Bacalah semua brosur ini dengan seksama sebelum anda mulai menggunakan obat ini karena mengandung informasi penting untuk Anda.
- Simpan leaflet ini. Anda mungkin perlu membacanya lagi.
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakan kepada dokter atau apoteker Anda.
- Obat ini hanya diresepkan untuk Anda. Jangan berikan kepada orang lain. Obat ini bisa membahayakan mereka.
- Jika anda mengalami efek samping, konsultasi ke dokter atau apoteker. Termasuk semua kemungkinan efek samping yang tidak tercantum dalam leaflet ini. Lihat bagian 4.

Apa yang tercantum dalam selebaran ini

1. Apa itu Slinda dan kegunaannya

Drospirenone Exeltis adalah pil kontrasepsi dan digunakan untuk mencegah kehamilan. Setiap blister Slinda mengandung 24 tablet putih, disebut sebagai tablet aktif, dan 4 tablet hijau, disebut sebagai tablet plasebo yang tidak mengandung zat aktif. Dua tablet warna berbeda disusun secara berurutan. Setiap 24 tablet aktif putih mengandung sejumlah kecil salah satu jenis hormon seks wanita, yaitu progestogen drospirenone. Karena itu Slinda disebut progestogen-only-pill (POP). Berlawanan dengan pil kombinasi, POPs tidak mengandung hormon estrogen selain progestogen. Untuk alasan ini, Slinda dapat digunakan oleh wanita yang sensitif estrogen. Slinda memberikan khasiat kontrasepsi yang tinggi. Efek kontrasepsi Slinda berdasarkan pada penghambatan ovulasi, perubahan cairan serviks dan efek pada endometrium, yang menjadi lebih tipis. Kerugiannya adalah perdarahan vaginal dapat terjadi pada interval yang tidak teratur selama penggunaan Slinda. Anda juga mungkin tidak mengalami pendarahan sama sekali.

2. Apa yang perlu anda ketahui sebelum menggunakan

Jangan gunakan Slinda:
- Jika anda alergi terhadap drospirenone atau bahan lain dari obat ini (tercantum di bagian 6).
- Jika anda memiliki pembekuan darah di dalam pembuluh darah misalnya di kaki (trombositosis vena dalam) atau paru-paru (emboli paru).
- Jika anda penderita atau pernah menderita penyakit liver dan fungsi liver anda masih belum normal.
- Jika ginjal anda tidak bekerja dengan baik (gagal ginjal).
- Jika anda memiliki atau diduga menderita kanker yang sensitif terhadap steroid seks, seperti jenis kanker payudara tertentu.
- Jika anda mengalami pendarahan vaginal yang tidak dapat dijelaskan.

Jika salah satu dari kondisi ini muncul saat menggunakan Slinda, segera hentikan penggunaan obat ini dan hubungi dokter.

Peringatan dan perhatian

Slinda, seperti kontrasepsi hormonal lainnya, tidak melindungi dari infeksi HIV (AIDS) atau penyakit menular seksual lainnya.
Konsultasikan dengan dokter sebelum mulai menggunakan Slinda jika salah satu dari kondisi berikut terjadi pada anda:
- Anda pernah mengalami trombosis (pembentukan pembekuan darah di dalam pembuluh darah).
- Anda menderita kanker hati, jika menderita penyakit kuning (kulit menguning) atau penyakit hati dan hati tidak bekerja secara normal.
- Anda pernah menderita kanker payudara.
- Anda penderita atau pernah menderita chloasma (bercak pigmentasi coklat kekuningan pada kulit, terutama di wajah); jika ini masalahnya, anda harus menghindari paparan sinar matahari atau radiasi ultraviolet selama penggunaan Slinda.
- Diabetes.
- Anda memiliki tekanan darah tinggi.
- Ginjal tidak bekerja dengan baik, karena dokter akan melakukan tes darah untuk memeriksa kadar kalium selama siklus pertama.

Jika kondisi tersebut memburuk atau pertama kali muncul kondisi tersebut, Anda harus menghubungi dokter. Dokter akan memutuskan apakah harus berhenti menggunakan Slinda dan mungkin menyarankan untuk menggunakan metode kontrasepsi non-hormonal.

Kanker payudara

Periksa payudara anda secara teratur dan hubungi dokter segera jika anda merasa ada benjolan di payudara.
Kanker payudara ditemukan sedikit lebih sering pada wanita yang menggunakan pil kombinasi dibandingkan pada wanita pada usia yang sama yang tidak menggunakan pil kombinasi. Jika wanita berhenti minum pil kombinasi, risikonya berangsur-angsur berkurang, sehingga 10 tahun setelah berhenti, risikonya sama dengan wanita yang tidak pernah minum pil kombinasi.
Kanker payudara jarang terjadi pada usia di bawah 40 tahun. Kanker payudara yang ditemukan pada wanita yang menggunakan pil kombinasi, tampaknya lebih kecil kemungkinannya untuk menyebar dibandingkan kanker payudara yang ditemukan pada wanita yang tidak menggunakan pil kombinasi. Tidak diketahui apakah perbedaan risiko kanker payudara disebabkan oleh pil kombinasi. Bisa jadi wanita lebih sering diperiksa, agar kanker payudara diketahui lebih dini.
Risiko kanker payudara pada pengguna sediaan yang hanya mengandung progestogen seperti Slinda diyakini serupa dengan wanita yang menggunakan pil kombinasi, tetapi buktinya kurang meyakinkan.

Trombosis (pembentukan pembekuan darah di pembuluh darah).

Segera temui dokter, jika anda menyadari adanya tanda-tanda trombosis (lihat juga 'Pemeriksaan rutin')

wanita yang menggunakan pil kombinasi, tetapi risikonya kurang meyakinkan.

Trombosis (pembentukan pembekuan darah di pembuluh darah).

Segera temui dokter, jika anda menyadari adanya tanda-tanda trombosis (lihat juga 'Pemeriksaan rutin').

Trombosis adalah pembentukan bekuan darah, yang dapat menyumbat pembuluh darah. Trombosis kadang-kadang terjadi pada vena dalam kaki (deep venous thrombosis). Jika gumpalan ini terlepas dari pembuluh darah di mana ia terbentuk, itu dapat menyumbat arteri paru-paru, menyebabkan apa yang disebut "emboli paru". Akibatnya, situasi fatal dapat terjadi.

Mungkin ada sedikit peningkatan risiko trombosis dengan sediaan yang hanya mengandung progestogen. Risiko trombosis lebih tinggi jika anggota keluarga anda (saudara kandung atau orang tua) telah mengalami trombosis pada usia yang relatif dini, dengan bertambahnya usia, obesitas, imobilisasi berkepanjangan, operasi besar atau trauma besar.

Tidak ada risiko nyata mengalami serangan jantung atau stroke (bekuan darah di otak) dengan sediaan yang hanya mengandung progestogen. Risikonya agak terkait dengan bertambahnya usia, peningkatan tekanan darah dan merokok.

Risiko stroke mungkin sedikit meningkat pada wanita dengan tekanan darah tinggi saat menggunakan sediaan yang hanya mengandung progestogen.

Gangguan jiwa:

Beberapa wanita yang menggunakan kontrasepsi hormonal termasuk Slinda telah melaporkan depresi atau suasana hati yang tertekan. Depresi bisa serius dan kadang-kadang dapat menyebabkan pikiran untuk bunuh diri. Jika Anda mengalami perubahan suasana hati dan gejala depresi, hubungi dokter sesegera mungkin untuk mendapatkan saran medis lebih lanjut.

Pemeriksaan kesehatan:

Sebelum Anda mulai menggunakan Slinda untuk pertama kalinya atau jika Anda memulai kembali pengobatan setelah beberapa lama tidak meminumnya, dokter akan menanyakan beberapa pertanyaan tentang kesehatan anda dan akan melakukan pemeriksaan fisik lengkap, termasuk pengukuran tekanan darah. Dokter akan memberi tahu seberapa sering anda harus melakukan kunjungan kontrol.

Anak-anak dan remaja

Slinda digunakan setelah menarche (menstruasi pertama wanita).

Obat-obat lain dan Slinda

Beri tahu dokter atau apoteker jika anda sedang mengonsumsi, baru saja mengonsumsi, atau mungkin sedang mengonsumsi obat lain. Mereka dapat menginformasikan anda jika perlu tindakan tambahan kontrasepsi (misalnya kondom) dan jika demikian, untuk beberapa lama, atau apakah penggunaan obat lainnya perlu diganti.

Beberapa obat:

- Dapat memiliki pengaruh pada kadar Slinda di dalam darah
- Dapat membuatnya kurang efektif dalam mencegah kehamilan
- Dapat menyebabkan pendarahan yang tidak terduga.

Ini termasuk obat-obatan yang digunakan untuk pengobatan:

- Dpilepsi (misalnya primidon, fenitoin, barbiturat, karbamazepin, oxcarbazepine, felbamate, topiramate);
- Tuberkulosis (misalnya rifampisin);
- Infeksi HIV (misalnya ritonavir, nelfinavir, nevirapine, efavirenz);
- Infeksi Virus Hepatitis C (misalnya boceprevir, telaprevir)
- Infeksi lain (griseofulvin);
- Tekanan darah tinggi pada pembuluh darah di paru-paru (bosentan);
- Depresi (obat herbal St. John's wort)
- Infeksi bakteri tertentu (misalnya klaritromisin, eritromisin)
- Infeksi jamur (misalnya flukonazol, itrakonazol, ketokonazol, vorikonazol)
- Tekanan darah tinggi (hipertensi), angina atau gangguan irama jantung tertentu (misalnya diltiazem)

Jika Anda sedang mengonsumsi obat-obatan dalam pengobatan jangka pendek yang mungkin membuat Slinda kurang efektif, metode kontrasepsi penghalang juga harus digunakan. Karena efek obat lain pada Slinda dapat bertahan hingga 28 hari setelah penghentian obat, maka perlu menggunakan metode kontrasepsi penghalang tambahan. Dokter dapat memberi tahu jika anda perlu tindakan tambahan kontrasepsi dan jika demikian, untuk beberapa lama. Jika anda mengonsumsi obat-obatan atau produk herbal setelah tablet aktif, buang tablet plasebo hijau dan mulai paket berikutnya dengan benar.

Jika anda mengonsumsi obat-obatan dalam jangka panjang yang mungkin membuat Slinda kurang efektif, dokter mungkin menyarankan Anda untuk menggunakan metode kontrasepsi non-hormonal.

Slinda juga dapat mengganggu efektifitas obat lain, misalnya:

- Siklosporin digunakan untuk pencegahan penolakan organ yang ditransplantasikan (efeknya dapat meningkat)
- Lamotrigin digunakan untuk epilepsi (efeknya mungkin berkurang)
- Diuretik tertentu (antagonis aldosteron, diuretik hemat kalium). Dokter mungkin merekomendasikan tes darah untuk memeriksa kadar kalium selama siklus pengobatan pertama dengan Slinda.

Slinda dengan makanan dan minuman

Hindari jus grapefruit atau buah grapefruit saat mengonsumsi Slinda.

Kehamilan

Jangan gunakan Slinda jika sedang hamil, atau mungkin sedang hamil.

Penggunaan Slinda sebelum atau selama kehamilan belum terbukti meningkatkan risiko pada saat persalinan. Namun, efek yang tidak diinginkan tidak dapat dikesampingkan.

Menyusui

Slinda dapat digunakan saat menyusui.

Diperkirakan tidak ada efek pada bayi baru lahir/bayi yang disusui. Namun, sejumlah kecil drospirenone diekskresikan dalam ASI.

Mengemudi dan menjalankan mesin

Tidak ada efek pada kemampuan mengemudi dan menggunakan mesin yang diamati pada pengguna kontrasepsi hormonal oral, meskipun tidak ada penelitian yang dilakukan dengan Slinda.

Slinda mengandung laktosa

Jika anda telah didiagnosa bahwa memiliki alergi terhadap beberapa gula, hubungi dokter sebelum menggunakan produk obat ini.

Pemeriksaan rutin

Saat menggunakan Slinda, dokter akan meminta Anda untuk melakukan pemeriksaan rutin. Secara umum, frekuensi dan sifat pemeriksaan rutin tergantung pada kondisi individual pasien.

Pemeriksaan rutin
Saat menggunakan Slinda, dokter akan meminta Anda untuk melakukan pemeriksaan rutin. Secara umum, frekuensi dan sifat pemeriksaan rutin tergantung pada kondisi individual pasien.

Hubungi dokter sesegera mungkin jika:
- Anda mengalami sakit parah atau bengkak di salah satu kaki, nyeri dada yang tidak dapat dijelaskan, sesak napas, batuk yang tidak biasa, terutama ketika anda batuk darah (mungkin mengindikasikan trombosis);
- Anda tiba-tiba mengalami sakit perut yang parah atau tampak sakit kuning (Anda mungkin melihat kulit dan bagian putih mata menguning atau urin berwarna gelap, mungkin mengindikasikan masalah hati);
- Anda merasakan benjolan di payudara Anda (mungkin mengindikasikan kanker payudara);
- Anda merasakan sakit yang tiba-tiba atau parah di perut bagian bawah atau daerah perut (mungkin mengindikasikan kehamilan ektopik, ini adalah kehamilan di luar kandungan);
- Anda akan diimobilisasi atau menjalani operasi (konsultasikan dengan dokter Anda setidaknya empat minggu sebelumnya);
- Anda mengalami pendarahan vagina yang tidak biasa dan berat;
- Anda curiga bahwa Anda hamil.

3. Bagaimana cara menggunakan Slinda
Selalu minum obat ini sesuai anjuran dokter. Konsultasikan ke dokter atau apoteker jika anda tidak yakin.
Setiap blister Slinda mengandung 24 tablet aktif putih dan 4 tablet plasebo hijau. Dua tablet berwarna berbeda disusun secara berurutan.
Minum satu tablet Slinda setiap hari dengan sedikit air, jika perlu. Anda dapat meminum tablet dengan atau tanpa makanan (Lihat bagian "Slinda dengan makanan dan minuman"). Anda harus minum tablet setiap pada waktu yang sama sepanjang hari sehingga interval antara dua tablet selalu 24 jam.
Jangan bingung antara tablet: Karena komposisi tablet yang berbeda, perlu untuk memulai dengan tablet putih pertama di kiri atas dan minum tablet setiap hari. Untuk urutan yang benar, ikuti arah panah dan urutan angka pada blister. Tablet pertama pengobatan harus diminum pada hari pertama perdarahan menstruasi. Setelah itu minum tablet terus menerus. Ambil tablet aktif putih selama 24 hari pertama dan kemudian tablet plasebo hijau selama 4 hari terakhir. Anda kemudian harus segera memulai paket baru tanpa istirahat dalam asupan tablet harian. Oleh karena itu tidak ada celah antara dua paket. Anda mungkin mengalami beberapa pendarahan selama penggunaan Slinda, atau anda mungkin juga tidak mengalami pendarahan sama sekali, tetapi anda harus terus meminum tablet anda seperti biasa tanpa gangguan. Jika anda menggunakan Slinda dengan cara ini, anda terlindungi dari kehamilan juga selama 4 hari saat anda menggunakan tablet plasebo.
Persiapan blister
Untuk membantu anda melacak, stiker 7 minggu masing-masing dengan 7 hari dalam seminggu disediakan ke dalam paket. Pilih stiker mingguan yang dimulai dengan hari anda mulai minum tablet (misalnya, jika anda mulai pada hari Kamis, gunakan stiker minggu yang dimulai dengan "THR") dan letakkan di kartu blister di atas kata-kata "Tempatkan label hari di sini" sehingga hari pertama berada di atas tablet bertanda "MULAI". Sekarang ada hari yang ditunjukkan di atas setiap tablet dan anda dapat melihat apakah anda telah meminum pil tertentu. Panah dan nomor berurutan menunjukkan urutan Anda untuk mengambil pil.
Memulai paket pertama Slinda
• *Jika Anda tidak menggunakan kontrasepsi hormonal pada bulan sebelumnya*
Mulailah dengan Slinda pada hari pertama menstruasi Anda. Saat melakukannya, Anda langsung terlindungi dari kehamilan dan Anda tidak perlu menggunakan tindakan perlindungan ekstra seperti kondom.
• *Saat mengganti dari pil kombinasi, cincin vaginal atau patch transdermal*
Anda harus memulai Slinda pada hari setelah tablet putih terakhir (tablet terakhir yang mengandung zat aktif) dari pil anda sebelumnya atau pada hari pelepasan penggunaan cincin vaginal atau patch transdermal (ini berarti tidak ada tablet, cincin, atau patch- istirahat). Jika anda mengikuti petunjuk ini, tindakan pencegahan kontrasepsi tambahan tidak diperlukan.
Anda juga dapat memulai Slinda selambat-lambatnya pada hari setelah jeda tablet, cincin, bebas patch atau plasebo yang biasa dari kontrasepsi Anda sebelumnya. Dalam hal ini, pastikan Anda menggunakan metode kontrasepsi penghalang tambahan selama 7 hari pertama penggunaan Slinda.
• *Saat mengganti progestogen-only pill (POP) lain*
Anda dapat mengganti setiap hari dari POP lain dan mulai menggunakan Slinda pada hari berikutnya. Tindakan pencegahan kontrasepsi tambahan tidak diperlukan.
• *Saat mengganti dari injeksi atau implan hanya progestogen atau dari sistem intrauterin pelepas progestogen (IUS)*
Anda harus memulai Slinda pada hari ketika injeksi berikutnya habis atau pada hari implan atau IUS anda dilepas. Tindakan pencegahan kontrasepsi tambahan tidak diperlukan.
• *Setelah melahirkan*
Anda dapat memulai Slinda setiap hari antara hari ke 21 hingga 28 setelah melahirkan. Jika Anda memulai lebih lambat dari hari ke 28 tetapi sebelum menstruasi kembali, anda harus yakin bahwa anda tidak hamil dan Anda harus menggunakan metode penghalang sebagai kondom sampai Anda menyelesaikan 7 hari pertama minum tablet. Informasi untuk wanita menyusui dapat ditemukan di bagian 2 (Kehamilan dan menyusui).
• *Setelah keguguran atau aborsi*
Anda harus mengikuti saran dari dokter Anda. Konsultasi ke dokter jika anda masih tidak yakin kapan harus memulai.
Jika anda meminum Slinda lebih banyak dari yang seharusnya
Belum ada laporan tentang efek berbahaya yang serius dari menggunakan terlalu banyak tablet Slinda pada satu waktu. Gejala yang mungkin terjadi adalah mual, muntah dan sedikit keluar darah dari vagina. Namun, dalam kasus overdosis, mintalah saran dokter karena tes darah harus dilakukan.
Jika anda lupa meminum Slinda
Anda harus minum tablet setiap hari sekitar waktu yang sama sepanjang hari sehingga interval antara dua tablet selalu 24 jam. Jika anda terlambat kurang dari 24 jam dalam meminum satu tablet, minum tablet yang terlewat segera setelah diingat dan minum tablet berikutnya pada waktu yang biasa, meskipun ini berarti minum dua tablet sekaligus. Jika anda terlambat lebih dari 24 jam dalam mengonsumsi tablet aktif putih, minumlah tablet yang terlupakan segera setelah anda ingat, meskipun itu berarti meminum dua tablet sekaligus dan menggunakan metode kontrasepsi tambahan (seperti kondom) selama 7 hari ke depan. Kemudian lanjutkan minum tablet seperti biasanya. Semakin banyak tablet berturut-turut yang Anda lewatkan, semakin tinggi risiko penurunan kemanjuran kontrasepsi. Jika anda lupa tablet di **minggu pertama** memulai tablet, dan Anda pernah berhubungan seks di minggu sebelum melupakan tablet, Anda harus menyadari bahwa ada risiko kehamilan. Dalam hal ini, hubungi dokter Anda. Jika anda lupa minum tablet **antara hari ke 15 - 24 (baris ketiga atau keempat)**, minumlah tablet yang terlupakan segera setelah Anda ingat, meskipun itu berarti anda harus meminum dua tablet sekaligus. Lanjutkan minum tablet aktif putih pada waktu yang biasa. Alih-alih mengambil tablet plasebo hijau pada strip ini, buanglah, dan mulai strip berikutnya (hari awal akan berbeda). Dengan melewatkan interval plasebo, perlindungan kontrasepsi dipertahankan. 4 tablet hijau terakhir di baris **ke-4** strip adalah tablet plasebo. Jika Anda melupakan salah satu tablet ini, ini tidak berpengaruh pada keandalan Slinda. Buang tablet plasebo yang terlupakan.

di baris **ke-4** strip adalah tablet plasebo. Jika Anda melupakan salah satu tablet ini, ini tidak berpengaruh pada keandalan Slinda. Buang tablet plasebo yang terlupakan.

Apa yang harus dilakukan jika muntah atau diare parah

Jika anda muntah atau diare berat, ada risiko zat aktif dalam pil tidak diserap sepenuhnya oleh tubuh anda, situasinya hampir sama dengan melupakan tablet. Dalam kasus ini, metode kontrasepsi tambahan mungkin diperlukan, mintalah saran dari dokter Anda.

Jika Anda muntah atau mengalami diare parah dalam waktu 3-4 jam setelah minum tablet aktif putih Slinda, Anda harus minum tablet putih lain dari kemasan blister lain sesegera mungkin. Jika memungkinkan, minumlah dalam waktu 24 jam dari saat Anda biasanya minum pil. Tindakan pencegahan kontrasepsi tambahan tidak diperlukan. Jika ini tidak memungkinkan atau 24 jam telah berlalu, Anda harus mengikuti saran yang diberikan di bagian "Jika Anda lupa minum Slinda" di atas.

Jika anda berhenti mengonsumsi Slinda

Anda dapat berhenti mengonsumsi Slinda kapan pun Anda mau. Sejak Anda berhenti, Anda tidak lagi terlindungi dari kehamilan. Jika Anda memiliki pertanyaan lebih lanjut tentang penggunaan obat ini, tanyakan kepada dokter atau apoteker atau perawat Anda.

4. Kemungkinan efek samping

Seperti semua obat-obatan, Slinda dapat menyebabkan efek samping, meskipun tidak semua orang mendapatkannya. Efek serius yang tidak diinginkan terkait dengan penggunaan Slinda dijelaskan dalam paragraf 'Kanker payudara' dan 'Trombosis' di bagian 2 'Yang perlu Anda ketahui sebelum menggunakan Slinda'. Silakan baca bagian ini untuk informasi tambahan dan konsultasikan dengan dokter Anda segera jika perlu.

Pendarahan vagina dapat terjadi pada interval yang tidak teratur selama penggunaan Slinda. Ini mungkin hanya sedikit pewarnaan yang bahkan mungkin tidak memerlukan pembalut, atau pendarahan yang lebih berat, yang terlihat seperti periode yang sedikit dan membutuhkan perlindungan sanitasi. Anda mungkin juga tidak mengalami pendarahan sama sekali. Pendarahan yang tidak teratur bukan merupakan tanda bahwa perlindungan kontrasepsi Slinda menurun. Secara umum, Anda tidak perlu mengambil tindakan apa pun; hanya terus mengambil Slinda. Namun, jika pendarahan berat atau berkepanjangan Anda harus berkonsultasi dengan dokter Anda.

Jika perdarahan sangat sering dan tidak teratur, metode kontrasepsi lain harus dipertimbangkan. Jika Anda tidak mengalami pendarahan vagina selama perawatan, Anda mungkin perlu melakukan tes kehamilan jika Anda belum meminum tablet sesuai dengan petunjuk di bagian 3 "Cara Mengkonsumsi Slinda".

Efek samping berikut telah dikaitkan dengan penggunaan Slinda:

Umum: dapat mempengaruhi hingga 1 dari 10 orang
- sakit kepala
- mual, sakit perut
- perubahan hasrat seksual, perubahan suasana hati
- jerawat
- rasa tidak nyaman pada payudara, nyeri haid, pendarahan dan haid tidak teratur
- penambahan berat badan

Jarang: dapat mempengaruhi hingga 1 dari 100 orang
- anemia (penurunan jumlah sel darah merah), kelelahan (kelelahan), retensi cairan
- pusing,
- muntah, diare, konstipasi
- infeksi vagina
- peningkatan jumlah berikut, ditunjukkan dalam tes darah: kalium, enzim hati (ALT, AST,GGT), bilirubin, creatine phosphokinase, trigliserida
- perubahan nafsu makan
- leiomioma uteri (tumor jinak rahim)
- suasana hati yang tertekan, depresi, kecemasan
- tidak adanya periode menstruasi, perubahan perdarahan menstruasi, nyeri panggul, kista ovarium, keputihan dan kekeringan
- rambut rontok, peningkatan keringat, gatal, ruam, seborrhoea (kulit berminyak), dermatitis (radang kulit)
- tekanan darah tinggi, hot flushes
- hipersensitivitas

Langka: dapat mempengaruhi hingga 1 dari 1.000 orang:
- intoleransi lensa kontak
- penurunan berat badan
- jumlah urin yang berlebihan
- kista payudara, sekresi payudara, apusan serviks abnormal, gatal-gatal genital

Pelaporan efek samping

Jika Anda mendapatkan efek samping, bicarakan dengan dokter atau apoteker Anda. Ini termasuk kemungkinan efek samping yang tidak tercantum dalam selebaran ini. Anda juga dapat melaporkan efek samping secara langsung melalui sistem pelaporan nasional yang tercantum dalam Appendix V:
https://www.ema.europa.eu/docs/en_GB/document_library/Template_or_form/2013/03/WC500139752.doc
atau melalui Farmakovigillans kami (email: pv.indonesia@exeltis.com ; Phone: +62-822-2517-7979). Dengan melaporkan efek samping Anda dapat membantu memberikan informasi lebih lanjut tentang keamanan obat ini.

5. Bagaimana cara menyimpan Slinda

Jauhkan obat ini dari pandangan dan jangkauan anak-anak.

Jangan gunakan obat ini setelah tanggal kedaluwarsa yang tertera pada dus dan blister setelah EXP. Tanggal kedaluwarsa mengacu pada hari terakhir bulan itu.

Simpan di bawah 30°C

Jangan membuang obat-obatan melalui air limbah atau limbah rumah tangga. Tanyakan apoteker Anda bagaimana membuang obat-obatan yang tidak lagi Anda gunakan. Langkah-langkah ini akan membantu melindungi lingkungan

Jangan membuang obat-obatan melalui air limbah atau limbah rumah tangga. Tanyakan apoteker Anda bagaimana membuang obat-obatan yang tidak lagi Anda gunakan. Langkah-langkah ini akan membantu melindungi lingkungan

6. Isi paket dan informasi lainnya

Apa isi Slinda

Tablet salut selaput putih aktif:

- Zat aktifnya adalah drospirenone.
  Setiap tablet salut selaput putih aktif mengandung 4 mg drospirenone.
- Bahan lainnya adalah:

Inti tablet: selulosa mikrokristalin; laktosa; silika, koloid (E551); magnesium stearat (E470b)
Lapisan tablet: poli (vinil alkohol); titanium dioksida (E171); Makrogol; bedak (E553b).

Tablet salut film plasebo hijau:

Tablet salut selaput plasebo hijau tidak mengandung zat aktif.
Inti tablet: laktosa monohidrat; tepung jagung; povidon; silika, koloid (E551); magnesium stearat (E470b)
Lapisan tablet: hypromellose (E464); triasetin; polisorbat 80 (E433); titanium dioksida (E171); Danau aluminium indigo carmine (E132); oksida besi kuning (E172)

Seperti apa Slinda dan isi paketnya

Setiap blister Slinda mengandung 24 tablet salut selaput aktif dan 4 tablet salut selaput plasebo.
Tablet aktif berbentuk bulat, tablet putih dengan huruf "E" dan "D" di sisi berlawanan, dengan diameter 5 mm.
Tablet plasebo berbentuk bulat, tablet hijau dengan huruf "E" dan angka "4" di sisi berlawanan, dengan diameter 5 mm.
Selain kotak karton, kotak karton untuk blister juga disertakan.
Slinda tersedia dalam kemasan kalender 1, 3, 6 dan 13 blister, masing-masing dengan 28 tablet.
Tidak semua ukuran kemasan dapat dipasarkan.

Reg No. DKI2138100617A1

HARUS DENGAN RESEP DOKTER

Diproduksi oleh:
Laboratorios Leon Frama, S.A.,
Navatejera, Spain

Diimpor oleh:
PT. Nufarindo,
Semarang, Indonesia

Slinda
Drospirenone
film-coated tablets 4 mg

Exeltis
Rethinking healthcare

LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Slinda is and what it is used for

Drospirenone Exeltis is a contraceptive pill and is used to prevent pregnancy. Each blister of Slinda contains 24 white tablets, also called active tablets, and 4 green tablets, also called placebo tablets, that do not contain active substance. The two differently coloured tablets are arranged in order. Each of the 24 white active tablets contains a small amount of one type of female sex hormone, the progestogen drospirenone. For this reason Slinda is called a progestogen-only-pill (POP). Contrary to the combined pills, POPs don't contain any oestrogen hormone next to the progestogen. For this reason, Slinda can be used by women who do not tolerate oestrogens. Slinda provides high contraceptive efficacy. The contraceptive effect of Slinda is based on the inhibition of ovulation, changes in the cervical mucus and effects on the endometrium, which becomes thinner.A disadvantage is that vaginal bleeding may occur at irregular intervals during the use of Slinda. You also may not have any bleeding at all.

2. What you need to know before you take Slinda

Do not take Slinda:
- If you are allergic to drospirenone or any of the other ingredients of this medicine (listed in section 6).
- If you have a blood clot in a blood vessel e.g. of the legs (deep venous thrombosis) or of the lungs (pulmonary embolism).
- If you have or have had a liver disease and your liver function is still not normal.
- If your kidneys are not working well (renal failure).
- If you have or are suspected to have a cancer that is sensitive to sex-steroids, such as certain types of breast cancer.
- If you have any unexplained vaginal bleeding.

If any of these conditions appear when using Slinda, stop taking this medicine immediately and contact your doctor.

Warnings and precautions

Slinda, like other hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease. Talk to your doctor before starting to use Slinda if any of the following conditions apply to you:
- You have ever had a thrombosis (formation of a blood clot in a blood vessel).
- You have liver cancer, if you have jaundice (yellowing of the skin) or liver disease and your liver is not working normally.
- You have ever had breast cancer.
- You have or have had chloasma (yellowish-brown pigmentation patches on the skin, particularly on the face); if this is the case, you will need to avoid exposure to the sun or ultraviolet radiation during treatment with Slinda.
- Diabetes.
- You have high blood pressure.
- Your kidneys are not working well, as your doctor will do a blood test to check potassium levels during the first cycle.

If you suffer a worsening or first appearance of any of these conditions, you should contact your doctor. Your doctor should then decide whether you should stop taking Slinda and may advice you to use a non-hormonal method of birth control.

Breast cancer

Regularly check your breasts and contact your doctor as soon as possible if you feel any lump in your breasts.

Breast cancer has been found slightly more often in women who take the combined Pill than in women of the same age who do not take the combined Pill. If women stop taking the combined Pill, the risk gradually decreases, so that 10 years after stopping the risk is the same as for women who have never taken the combined Pill.

Breast cancer is rare under 40 years of age. Breast cancers found in women who take the combined Pill, seem less likely to spread than breast cancers found in women who do not take the combined Pill. It is not known whether the difference in breast cancer risk is caused by the combined Pill. It may be that the women were examined more often, so that the breast cancer is noticed earlier.

The risk of breast cancer in users of progestogen-only preparations like Slinda is believed to be similar to that in women who use the combined Pill, but the evidence is less conclusive.

Thrombosis (*formation of a blood clot in a blood vessel*).

Thrombosis (*formation of a blood clot in a blood vessel*).
See your doctor immediately, if you notice possible signs of a thrombosis (see also 'Regular check-ups').
Thrombosis is the formation of a blood clot, which may block a blood vessel. A thrombosis sometimes occurs in the deep veins of the legs (deep venous thrombosis). If this clot breaks away from the veins where it is formed, it may reach and block the arteries of the lungs, causing a so-called "pulmonary embolism". As a result, fatal situations may occur.
There may be a slightly increased risk of thrombosis with progestogen-only preparation. The risk of thrombosis is higher if a member of your family (a sibling or a parent) has had thrombosis at an relatively early age, with increasing age, obesity, prolonged immobilization, major surgery or major trauma.
There is no apparent risk of having a heart attack or stroke (a blood clot in the brain) with a progestogen-only preparation. The risk is rather related to increasing age, increase in blood pressure and smoking.
The risk of stroke may be slightly increased in women with high blood pressure when taking progestogen-only preparations.
Psychiatric disorders:
Some women using hormonal contraceptives including Slinda have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.
Medical examination:
Before you start taking Slinda for the first time or if you re-start the treatement after some time of not taking it, your doctor will ask you some questions about your health and will do a complete physical examination, including blood pressure measurements. Your doctor will tell you how often you should go for control visits.

Children and adolescents
Slinda is used after menarche (the first menstrual bleeding of a woman).

Other medicines and Slinda
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. They can tell you if you need take additional contraceptive precautions (for example condoms) and if so, for how long, or wheter the use of another medicine you need must be changed.
Some medicines:
- Can have an influence on the blood levels of Slinda
- Can make it less effective in preventing pregnancy
- Can cause unexpected bleeding.

These include medicines used for the treatment of:
- Epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, felbamate, topiramate);
- Tuberculosis (e.g. rifampicin);
- HIV infections (e.g. ritonavir, nelfinavir, nevirapine, efavirenz)
- Hepatitis C Virus infections (e.g. boceprevir, telaprevir)
- Other infections (griseofulvin);
- High blood pressure in the blood vessels in the lungs (bosentan);
- Depressive mood (the herbal remedy St. John's wort)
- Certain bacterial infections (e.g. clarithromycin, erythromycin)
- Fungal infections (e.g. fluconazole, itraconazole, ketoconazole, voriconazole)
- High blood pressure (hypertension), angina or certain heart rhythm disorders (e.g. diltiazem)

If you are taking medicines in a short-term treatment that might make Slinda less effective, a barrier contraceptive method should also be used. Since the effect of another medicine on Slinda may last up to 28 days after stopping the medicine, it is necessary to use the additional barrier contraceptive method for that long. Your doctor can tell you if you need to take additional contraceptive precautions and if so, for how long. If your are taking medicines or herbal products beyond the end of the white active tablets, discard the green placebo tablets and start the next pack right away. If you are taking medicines in a long-term treatment that might make Slinda less effective, your doctor may advise you to use a non-hormonal method of birth control. Slinda may also interfere with how other medicines work e.g:
- Ciclosporine used to prevent rejection of transplanted organs (the effect may be increased)
- Lamotrigine used for epilepsy (the effect may be decreased)
- Certain diuretics (aldosterone antagonists, potassium-sparing diuretics). Your doctor may recommend a blood test to check potassium levels during the first treatment cycle with Slinda.

Slinda with food and drink
Avoid grapefruit or grapefruit juice while you are taking Slinda.

Pregnancy
Do not use Slinda if you are pregnant, or think you may be pregnant.
Use of Slinda prior or during pregnancy has not shown to increase risk of birth deffects. However, undesirable effects cannot be excluded.

Breast-feeding
Slinda may be used while you are breast-feeding.
No effects on the breastfed newborns/infants are anticipated. However, very small amounts of drospirenone are excreted in the breast milk.

Driving and using machines
No effects on ability to drive and use machines are observed in users of oral hormonal contraceptives, although no studies have been performed with Slinda.

Slinda contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Regular check-ups
When you are using Slinda, your doctor will tell you to return for regular check-ups. In general, the frequency and nature of these check-ups will depend on your personal situation.

Regular check-ups
When you are using Slinda, your doctor will tell you to return for regular check-ups. In general, the frequency and nature of these check-ups will depend on your personal situation.

Contact your doctor as soon as possible if:
- You have severe pain or swelling in either of your legs, unexplained pains in the chest, breathlessness, an unusual cough, especially when you cough up blood (possibly indicating a thrombosis);
- You have a sudden, severe stomach ache or look jaundiced (you may notice yellowing of the skin and the whites of the eyes or dark urine, possibly indicating liver problems);
- You feel a lump in your breast (possibly indicating breast cancer);
- You have a sudden or severe pain in the lower abdomen or stomach area (possibly indicating an ectopic pregnancy, this is a pregnancy outside the womb);
- You are to be immobilised or are to have surgery (consult your doctor at least four weeks in advance);
- You have unusual, heavy vaginal bleeding;
- You suspect that you are pregnant.

3. How to take Slinda
Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
Each blister of Slinda contains 24 white active tablets and 4 green placebo tablets. The two differently coloured tablets are arranged in order.
Take one tablet of Slinda every day with a little water if necessary. You may take the tablets with or without food (See section "Slinda with food and drink"). You must take the tablets everyday around the same time of the day so that the interval between two tablets is always 24 hours.
Do not confuse the tablets: Because of the different composition of the tablets it is necessary to begin with the first white tablet on the upper left and to take the tablets every day. For the correct order, follow the direction of the arrows and the sequence of numbers on the blister.
The first tablet of the treatment should be taken on the first day of menstrual bleeding. Thereafter tablet taking is continous. Take a white active tablet for the first 24 days and then a green placebo tablet for the last 4 days. You must then start a new pack straightaway without a break in daily tablet intake. There is therefore no gap between two packs.
You may have some bleedings during the use of Slinda, or you may also have no bleeding at all, but you must continue to take your tablets as normal without interruption.
If you use Slinda in this manner, you are protected against pregnancy also during the 4 days when you are taking a placebo tablet.
Preparation of the blister
To help you keep track, 7 week stickers each with the 7 days of the week are provided into the pack. Choose the week sticker that starts with the day you begin taking the tablets (for example, if you start on a Thursday, use the week sticker that starts with "THR") and place it on the blister card over the words "Place day label here" so that the first day is above the tablet marked "START". There is now a day indicated above every tablet and you can see whether you have taken a certain pill. The arrows and the consecutive numbers show the order you are to take the pills.
Starting your first pack of Slinda
- *If you have not used a hormonal contraceptive in the previous month*
  Begin with Slinda on the first day of your period. When doing so, you are immediately protected against pregnancy and you do not need to use extra protective measures such as a condom.
- *When changing from a combined pill, vaginal ring or transdermal patch*
  You should start Slinda on the day after the last active tablet (the last tablet containing the active substances) of your previous pill or on the day of removal of your vaginal ring or transdermal patch (this means no tablet-, ring- or patch-free break). If you follow these instructions, additional contraceptive precautions are not necessary.
  You can also start Slinda at the latest on the day following the usual tablet-, ring-, patch-free break or placebo interval of your previous contraceptive. In this case, make sure you use an additional barrier method of contraception for the first 7 days of Slinda taking.
- *When changing from another progestogen-only pill (POP)*
  You may switch any day from other POP and start taking Slinda the next day. Additional contraceptive precautions are not necessary.
- *When changing from a progestogen-only- injection or implant or from a progestogen-releasing intrauterine system (IUS)*
  You should start Slinda the day when the next injection is due or on the day that your implant or your IUS is removed.
  Additional contraceptive precautions are not necessary.
- *After having a baby*
  You can start Slinda any day between day 21 to 28 after having your baby. If you start later than day 28 but before the menstruation have returned, you must be sure that you are not pregnant and you must use a barrier method as a condom until you have completed the first 7 days of tablet-taking.
  Information for breast-feeding women can be found in section 2 (Pregnancy and breast-feeding).
- *After miscarriage or an abortion*
  You should follow the advice of your doctor.

Ask your doctor if you are still not sure when to start.
If you take more Slinda than you should
There have been no reports of serious harmful effects from taking too many Slinda tablets at one time. Symptoms that may occur are nausea, vomiting and slight vaginal bleeding.
However, in case of overdose, ask your doctor for advice because blood tests should be done.
If you forget to take Slinda
You must take the tablets everyday around the same time of the day so that the interval between two tablets is always 24 hours. If you are less than 24 hours late in taking any single tablet, take the missed tablet as soon as it is remembered and take the next tablet at the usual time, even if this means taking two tablets at the same time. If you are more than 24 hours late in taking any white active tablet, take the missed tablet as soon as it is remembered, even if this means taking two tablets at the same time, and use an additional method of contraception (such as a condom) for the next 7 days. Then continue taking the tablets at your usual time. The more consecutive tablets you have missed, the higher the risk that the contraceptive efficacy is decreased.
If you have forgotten a tablet in the **first week** starting the tablets, and you have had sex in the week before forgetting the tablet you must realize that there is a risk of pregnancy. In that case, contact your doctor. If you forgot to take the tablet **between days 15 - 24 (third or fourth row)**, take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the white active tablets at the usual time. Instead of taking the green placebo tablets on this strip, throw them away, and start the next strip (the starting day will be different). By skipping the placebo interval, the contraceptive protection is maintained. The last 4 green tablets in the **4th** row of the strip are the placebo tablets. If you forget one of these tablets, this has no effect on the reliability of Slinda. Throw away the forgotten placebo tablet.

this strip, throw them away, and start the next strip (the starting day will be different). By skipping the placebo interval, the contraceptive protection is maintained. The last 4 green tablets in the **4th** row of the strip are the placebo tablets. If you forget one of these tablets, this has no effect on the reliability of Slinda. Throw away the forgotten placebo tablet.

What to do in the case of vomiting or severe diarrhea

If you vomit or have severe diarrhea, there is a risk that the active substance in the pill will not be fully absorbed by your body, the situation is almost the same as forgetting a tablet. In these cases, an additional method of contraception may be needed, ask your doctor for advice.

If you vomit or have severe diarrhea within 3-4 hours after taking your white active tablet of Slinda, you must take another white tablet from another blister pack as soon as possible. If possible, take it within 24 hours of when you normally take your pill. Additional contraceptive precautions are not necessary. If this is not possible or 24 hours have passed, you should follow the advice given in the section "If you forget to take Slinda" above.

If you stop taking Slinda

You can stop taking Slinda whenever you want. From the day you stop you are no longer protected against pregnancy.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

4. Possible side effects

Like all medicines, Slinda can cause side effects, although not everybody gets them.

Serious undesirable effects associated with the use of Slinda are described in the paragraphs 'Breast cancer' and 'Thrombosis' in section 2 'What you need to know before you take Slinda'. Please read this section for additional information and consult your doctor at once where appropriate.

Vaginal bleeding may occur at irregular intervals during the use of Slinda. This may be just slight staining which may not even require a pad, or heavier bleeding, which looks rather like a scanty period and requires sanitary protection. You may also not have any bleeding at all. The irregular bleedings are not a sign that the contraceptive protection of Slinda is decreased. In general, you need not take any action; just continue to take Slinda. If, however, bleeding is heavy or prolonged you should consult your doctor.

If the bleeding is very frequent and irregular, another contraceptive method should be considered. If you don't have vaginal bleeding during the treatment, you may need to do a pregnancy test if you have not taken the tablets in accordance with the instructions in section 3 "How to take Slinda" .

The following side effects have been associated with the use of Slinda :

Common: may affect up to 1 in 10 people

- headache
- nausea, abdominal pain
- changes in sexual desire, altered mood
- acne
- breast discomfort, painful periods, bleeding and irregular menstrual periods
- weight gain

Uncommon: may affect up to 1 in 100 people

- anaemia (decreased number of the red blood cells), fatigue (tiredness), fluid retention
- dizziness,
- vomiting, diarrhea, constipation
- vaginal infections
- increased amount of the following, shown in blood tests: potassium, liver enzymes (ALT, AST, GGT), bilirubin, creatine phosphokinase, triglycerides
- appetite changes
- uterine leiomyoma (benign tumor of the uterus)
- depressed mood, depression, anxiety
- absence of menstrual periods, altered menstrual bleeding, pelvic pain, ovarian cysts, vaginal discharge and dryness
- hair loss, increased sweating, itching, rash, seborrhoea (greasy skin), dermatitis (inflammation of the skin)
- elevated blood pressure, hot flushes
- hypersensitivity

Rare: may affect up to 1 in 1,000 people:

- contact lens intolerance
- weight loss
- excessive amount of urine
- breast cyst, breast secretion, abnormal cervical smear, genital itching

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V :

https://www.ema.europa.eu/docs/en_GB/document_library/Template_or_form/2013/03/WC500139752.doc

or to our Pharmacovigilance Department (email: pv.indonesia@exeltis.com ; Phone: +62-822-2517-7979). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Slinda

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Store below 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Slinda contains

White active film-coated tablets:

- The active substance is drospirenone.

Each white active film-coated tablet contains 4 mg of drospirenone.

- The other ingredients are:

Tablet core: microcrystalline cellulose ; lactose; silica, colloidal (E551); magnesium stearate (E470b).
Tablet coat: poly (vinyl alcohol); titanium dioxide (E171); Macrogol; talc (E553b)

Green placebo film-coated tablets:

The green placebo film-coated tablets do not contain active substance.
Tablet core: lactose monohydrate; maize starch; povidone; silica, colloidal (E551); magnesium stearate (E470b)
Tablet coat: hypromellose (E464); triacetin; polysorbate 80 (E433); titanium dioxide (E171); Indigo carmine aluminium lake (E132); yellow iron oxide (E172)

What Slinda looks like and contents of the pack

Each blister of Slinda contains 24 active film-coated tablets and 4 placebo film-coated tablets.
The active tablet is a round, white tablet with the letters "E" and "D" debossed on opposite sides, with a diameter of 5 mm.
The placebo tablet is a round, green tablet with the letter "E" and the number "4" debossed on opposite sides, with a diameter of 5 mm.
In addition to the carton box, a carton case for the blister is enclosed.
Slinda is available in calendar-packs of 1, 3, 6 and 13 blisters, each with 28 tablets.
Not all pack sizes may be marketed.

Reg No. DKI2138100617A1

ON MEDICAL PRESCRIPTION ONLY

Manufactured by:
Laboratorios Leon Frama, S.A.,
Navatejera, Spain

Imported by:
PT. Nufarindo,
Semarang, Indonesia