รุ่น Indo

Old code : 991-546-133
New code : 991-546-xxx

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BSPA/OLIC0251A
Utrogestan
Leaflet
Dimension 179x296 mm
Paper Weight 60 gsm
Print 1 Colors

15/03/2019
23/10/2019

Halaman depan

UTROGESTAN® 100 mg Micronised progesterone
UTROGESTAN® 200 mg Micronised progesterone

Read this entire leaflet before you start taking this medicine.
If you have any questions, if you any doubt, please ask your doctor.

COMPOSITION
The active substance is : micronised progesterone.
Excipients of the contents the capsule : sun flower oil, soya-bean lecithin.
Constituents of the capsules : gelatin, glycerol, titanium dioxide (E 171).

PHARMACEUTICAL FORM-PACKING SIZE
UTROGESTAN® 100 mg : box of 30 capsules
UTROGESTAN® 200 mg : box of 15 capsules

INDICATIONS
Utrogestan® is prescribed for disorder related to a progesterone deficit:
By oral route:
- Menstrual irregularity due to dysovulation,
By vaginal route:
- During in Vitro fertilization cycles (IVF).
For all other Progesterone indications, the vaginal route represents an alternative to the oral route, in case of adverse events due to Progesterone (somnolence, dizziness).

POSOLOGY AND METHOD OF ADMINISTRATION
Utrogestan® should not be taken more than 200 mg per intake (two 100 mg capsules or one 200 mg capsule), by oral or vaginal route.
On average for progesterone insufficiencies, the daily dose is 200 to 300 mg divided into one or two intakes, 100 mg in the morning, and 100 mg or 200 mg at bedtime. In some case, notably to help pregnancy, doctor may has to increase the dose to 600 mg per day, divided into three intakes.
Treatment may be prescribed continuously, or sequentially for some days per month, and possibly associated with estrogen therapy. Two routes of administration are possible, oral and vaginal.
If the medicine is to be administered orally : swallow the capsule(s) with a glass of water far from mealtime, in one to three intakes, following doctor's prescription.
If the medicine is to be administered vaginally : insert each capsule deeply in the vagina.
Duration of treatment
The duration of the treatment will be specified by the doctor, according to the case. The duration of treatment may be readjusted by the doctor depending on the indication and efficacy or treatment.
Children
Not applicable

CONTRAINDICATIONS
Known allergy or hypersensitivity to progesterone or to any of the excipients. The capsule contain sun flower oil and should never be used by patients allergic to sun flower. Severe hepatic dysfunction, undiagnosed vaginal bleeding, mammary or genital tract carcinoma. Thrombophlebitis, thromboembolic disorder, Cerebral hemorrhage, porphyria.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE
Warnings :
Utrogestan® Capsules are not a treatment for premature labour.
Prescription of progesterone beyond the first trimester of pregnancy may reveal gravidic cholestasis.
Utrogestan® Capsules are not suitable for use as a contraceptive.
If unexplained, sudden or gradual, partial or complete loss of vision, proptosis or diplopia, papilloedema, retinal vascular lesions or migraine occur during therapy, the drug should be discontinued and appropriate diagnostic and therapeutic measures instituted.
Utrogestan® Capsules are intended to be co-prescribed with an estrogen product as HRT. Epidemiological evidence suggests that the use of HRT is associated with an increased risk of developing deep vein thrombosis (DVT) or pulmonary embolism. The prescribing information for the co-prescribed estrogen product should be referred to for information about the risks of venous thromboembolism.
There is suggestive evidence of a small increased risk of breast cancer with estrogen replacement therapy. It is not known whether concurrent progesterone influences the risk of cancer in post-menopausal women taking hormone replacement therapy. The prescribing information for the co-prescribed estrogen product should be referred to for information about the risks of breast cancer.
Precautions :
Prior to taking hormone replacement therapy (and at regular intervals thereafter) each woman should be assessed. A personal and family medical history should be taken and physical examination should be guided by this and by the contraindications and warnings for this product.
Utrogestan® Capsules should not be taken with food and should be taken at bedtime. Concomitant food ingestion increases the bioavailability of Utrogestan® Capsules.
Utrogestan® Capsules should be used cautiously in patients with conditions that might be aggravated by fluidretention (e.g. hypertension, cardiac disease, renal disease, epilepsy, migraine, asthma); in patients with a history of depression, diabetes, mild to moderate hepatic dysfunction, migraine or photosensitivity and in breast-feeding mothers.
Clinical examination of the breasts and pelvic examination should be performed where clinically indicated rather than as a routine procedure. Women should be encouraged to participate in the national breast cancer screening programme (mammography) and the national cervical cancer screening programme (cervical cytology) as appropriate for their age. Breast awareness should also be encouraged and women advised to report any changes in their breasts to their doctor or nurse.

Halaman belakang

INTERACTION WITH OTHER MEDICAL PRODUCTS AND OTHER FORMS OF INTERACTION
Utrogestan® Capsules may interfere with the effects of bromocriptine and may raise the plasma concentration of cyclosporine.
Utrogestan® Capsules may affect the results of laboratory tests of hepatic and/or endocrine functions.
Metabolism of Utrogestan® Capsules is accelerated by rifamycin an antibacterial agent.
The metabolism of progesterone by human liver microsomes was inhibited by ketoconazole (IC_{50} <0.1 µm) Ketoconazole is a known inhibitor of cytochrome P450 3A4. These data therefore suggest that ketoconazole may increase the bioavailability of progesterone. The clinical relevance of the in vitro findings is unknown.

PREGNANCY AND LACTATION
Pregnancy
The use of Utrogestan® soft capsules is not contraindicated during pregnancy including the first few weeks.
Lactation
Detectable amounts of progesterone enter the breast milk. There is no indication for prescribing HRT during lactation.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
Utrogestan® Capsules may cause drowsiness and/or dizziness in a minority of patients; therefore caution is advised in drivers and users of machines. Taking the capsules at bedtime should reduce these effects during the day.

UNDESIRABLE EFFECTS
Somnolence or transient dizziness may occur 1 to 3 hours after intake of the drug. Bedtime dosing and reduction of the dose may reduce these effects.
Shortening of the cycle or breakthrough bleeding may occur if the treatment sequence is initiated too early particularly before cycle day 1. If this occurs, the dose of Utrogestan® Capsules can be reduced and taken at bedtime from day 1 to day 26 of each therapeutic cycle.
Acne, urticaria, rashes, fluid retention, weight changes, gastro-intestinal disturbances, changes in libido, breast discomfort, premenstrual symptoms, menstrual disturbances; also chloasma, depression, pyrexia, insomnia, alopecia, hirsutism; rarely jaundice. Venous thromboembolism, i.e. deep leg or pelvic venous thrombosis and pulmonary embolism, is more frequent among hormone replacement therapy users than among non-users.
After vaginal administration, local irritation may occur (due to the presence of soya lecithin, sun flower oil). The following effect have been reported in associated with soft capsules administered via the oral route.
Common undesirable effects : altered menstrual cycles, amenorrhea, intermenstual bleeding, headaches.
Uncommon undesirable effects : drowsiness, transient dizziness, cholestatic jaundice, pruritus, gastrointestinal disorder.

OVERDOSE
Symptoms of over dosage may include somnolence, dizziness, euphoria or dysmenorrhoea. Treatment is observation and, if necessary, symptomatic and supportive measures should be provided.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties
Pharmacotherapeutic group (ATC code: G03DA04 : Genito-urinary system and sex hormones)
Progesterone is a natural progestogen, the main hormone of the corpus luteum and the placenta. It acts on the endometrium by converting the proliferating phase to the secretory phase. Utrogestan® Capsules have all the properties of endogenous progesterone with induction of a full secretory endometrium and in particular gestagenic, antiestrogenic, slightly anti-androgenic and antialdosterone effects.
Pharmacokinetic properties
Absorption:
Micronised progesterone is absorbed by the digestive tract. Pharmacokinetic studies conducted in healthy volunteers have shown that after oral administration of 2 capsules (200mg), plasma progesterone levels increased to reach the Cmax of 13.8ng/ml +/- 2.9ng/ml in 2.2 +/- 1.4 hours. The elimination half-life observed was 16.8+/- 2.3 hours.
Although there were inter-individual variations, the individual pharmacokinetic characteristics were maintained over several months, indicating predictable responses to the drug.
Distribution
Progesterone is approximately 96%-99% bound to serum proteins, primarily to serum albumin (50%-54%) and transcortin (43%-48%).
Elimination
Urinary elimination is observed for 95% in the form of glycuroconjugated metabolites, mainly 3 α, 5 β–pregnanediol (pregnandiol).
Metabolism
Progesterone is metabolised primarily by the liver. The main plasma metabolites are 20 α hydroxy- 4 α- prenolone and 5 α-dihydroprogesterone. Some progesterone metabolites are excreted in the bile and these may be deconjugated and further metabolized in the gut via reduction, dehydroxylation and epimerization. The main plasma and urinary metabolites are similar to those found during the physiological secretion of the corpus luteum.

STORAGE, SHELF-LIFE
Keep out of the reach and sight of children.
Do not use after expiry date stated on the blister and the box.
Store in below 30°C and dry place, protect from light.
Shelf-life : 36 months from manufacturing date.

ON MEDICAL PRESCRIPTION ONLY
HARUS DENGAN RESEP DOKTER

PRESENTATIONS
Utrogestan® 100 mg : box of 2 blister @ 15 capsules — Reg. No. DKIxxxxxxxxxxx
Utrogestan® 200 mg : box of 1 blister @ 8 capsules + 1 blister @ 7 capsules — Reg. No. DKIxxxxxxxxxxx

Manufactured by: OLIC (Thailand) Limited, Thailand

BESINS HEALTHCARE

Imported by: PT Sydna Farma, Jakarta, Indonesia

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DISETUJUI OLEH BPOM: 20/04/2020

EREG10021912000012, EREG10021912000013