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Gynprogest

Progesterone

Soft Capsules

COMPOSITION
 Each capsule contains 100 mg micronized Progesterone.
 Each capsule contains 200 mg micronized Progesterone.

APPEARANCE
 Gynprogest 100 soft capsules : ovoid capsules, off-white colored.
 Gynprogest 200 soft capsules : ovoid capsules, off-white colored.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties
 Pharmacotherapeutic group (ATC code: G03DA04 : Genito-urinary system and sex hormones).
 Progesterone is a natural progesterone, the main hormone of the corpus luteum and the placenta. It acts on the endometrium by converting the proliferating phase to the secretory phase. Gynprogest capsules have all the properties of endogeneous progesterone with induction of a full secretory endometrium and in particular gestagenic, antiestrogenic, slightly anti-androgenic and antialdosterone effects.

Pharmacokinetics properties
Absorption
 Micronised progesterone is absorbed by the digestive tract. Pharmacokinetic studies conducted in healthy volunteers have shown that oral administration of 2 capsules (200 mg), plasma progesterone levels increased to reach the Cmax of 13.8 ng/ml +/- 2.9 ng/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 glycuconjugated metabolites, mainly 3a, 5 B-pregnadiol (pregnadiol).

Metabolism
 Progesterone is metabolised primarily by the liver. The main plasma metabolites are 20 a hydroxy-4a-prenolone and 5 a-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.

INDICATIONS



Exeltis
Rethinking healthcare

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INDICATIONS

Gynprogest 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).

CONTRAINDICATIONS

Known allergy or hypersensitivity to progesterone or to any of the excipients. The capsule contain arachis oil (peanut oil) and should never be used by patients allergic to peanuts. Severe hepatic dysfunction, undiagnosed vaginal bleeding, mammary or genital tract carcinoma. Thrombophlebitis, thromboembolic disorder, cerebral hemorrhage, porphyria.

DOSAGE AND ADMINISTRATION

Gynprogest 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.

WARNINGS AND PRECAUTIONS

Warnings

Gynprogest are not a treatment for premature labour.

Prescription of progesterone beyond the first trimester of pregnancy may reveal gravidic cholestasis.

Gynprogest 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 occurs during therapy, the drug should be discontinued and appropriate diagnostic and therapeutic measures instituted.

Gynprogest 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.

170 mm

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202 mm

222 mm

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.

Gynprogest should not be taken with food and should be taken at bedtime. Concomitant food ingestion increases the bioavailability of Gynprogest.

Gynprogest should be used cautiously in patients with conditions that might be aggravated by fluid retention (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 breastfeeding 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.

Pregnancy And Lactation

Pregnancy

The use of Gynprogest 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

Gynprogest 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 Gynprogest 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, peanut oil). The following effects have been reported in associated with soft capsules administered via the oral route.

Common undesirable effects: altered menstrual cycles, amenorrhea, intermenstrual bleeding, and headaches.

Uncommon undesirable effects: drowsiness, transient dizziness, cholestatic jaundice, pruritus, gastrointestinal disorder.

Reporting of Adverse Effect

Reporting of Adverse Effect

Reporting suspected side effects after a product has received a marketing authorization is important. This allows for continued monitoring of the product's benefit/risk balance. Health professional are encouraged to report all side effects to our Pharmacovigilance Department (email: pv.indonesia@exeltis.com ; Phone: +62-822-2517-7979) or report to Pharmacovigilance Center/ MESO National DITWAS KMEI ONAPPZABPOM (email: pv-center@pom.go.id ; Phone: +62-21-4244691 Ext. 1079 ; Website: <https://e-meso.pom.go.id/ADR>).

EXCIPIENT LIST

Capsule content : Peanut oil, Soy lecithin. Capsule shell : Gelatine, Purified water, Glycerol, Titanium dioxide.

DRUG INTERACTIONS

Gynprogest may interfere with the effects of bromocriptine and may raise the plasma concentration of cyclosporine. Gynprogest may affect the results of laboratory tests of hepatic and/or endocrine functions.

Metabolism of Gynprogest is accelerated by rifampicin an antibacterial agent.

The metabolism of progesterone by human liver microsomes was inhibited by ketoconazole (IC₅₀ <0.1 µm). Ketoconazole is a known inhibitor of cytochrome P450 3A4. Therefore ketoconazole may increase the bioavailability of progesterone.

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.

STORAGE

Keep out of the reach and sight of children

Do not use after expiry date stated on the blister and the box

Store below 30° C and dry place, protect from the light

PRESENTATIONS

Gynprogest 100 mg: Box, 2 blisters @ 15 soft capsules

Reg.No.DKI2238100702A1

Gynprogest 200 mg: Box, 1 blister @ 15 soft capsules

Reg.No.DKI2238100702B1

**HARUS DENGAN RESEP DOKTER
ON MEDICAL PRESCRIPTION ONLY**

Manufactured by:

Laboratorios Leon Farma S.A

Spain

Imported by:

PT. Nufarindo

Semarang - Indonesia

LEÓN CODE



10 mm

2 mm

10 mm

2 mm

Gynprogest

Progesterone

Soft Capsules



Leaflet : Informasi untuk pengguna

Bacalah semua leaflet ini dengan seksama sebelum Anda mulai minum obat ini karena di dalamnya mengandung informasi penting untuk Anda.

- Simpan selebaran 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 itu kepada orang lain. Hal itu dapat membahayakan mereka, bahkan jika tanda-tanda penyakit mereka sama dengan Anda.
- Jika Anda mendapatkan efek samping, bicarakan dengan dokter atau apoteker Anda. Ini termasuk semua kemungkinan efek samping yang tidak tercantum dalam brosur ini.

Dalam leaflet ini:

1. Apa itu GYNPROGEST dan digunakan untuk apa
2. Apa yang perlu Anda ketahui sebelum Anda mengambil / menggunakan GYNPROGEST
3. Cara mengambil / menggunakan GYNPROGEST
4. Interaksi Obat
5. Kemungkinan efek samping
6. Bagaimana cara menyimpan GYNPROGEST
7. Isi kemasan dan informasi lainnya

1. Apa itu GYNPROGEST dan digunakan untuk apa

GYNPROGEST termasuk dalam kelompok obat yang disebut progestogen dan mengandung progestogen alami. Obat ini digunakan untuk gangguan yang terkait dengan kekurangan progesteron, terapi penggantian hormon untuk menopause dan untuk membantu beberapa masalah kesuburan.

2. Yang perlu Anda ketahui sebelum mengambil GYNPROGEST **Jangan mengambil / menggunakan GYNPROGEST**

- Jika Anda alergi (hipersensitif) terhadap zat aktif atau bahan lain di dalamnya GYNPROGEST termasuk dalam bagian 6.
- Produk obat ini mengandung minyak kacang tanah. Ini tidak boleh digunakan jika pasien alergi kacang atau kedelai.
- Jika Anda mengalami perdarahan vagina yang tidak terdiagnosis.
- Jika Anda memiliki masalah hati yang parah (hanya pemberian oral).
- Jika Anda memiliki riwayat gangguan tromboemboli.

Peringatan dan pencegahan

Peringatan dan pencegahan

Mintalah saran dokter atau apoteker Anda sebelum menggunakan GYNPROGEST.

Jika kantuk terjadi, kapsul harus diminum sebelum tidur.

Diambil sesuai dengan dosis dan kondisi penggunaan yang dianjurkan, pengobatan tidak memiliki efek kontrasepsi.

Obat lain dan GYNPROGEST

Beri tahu dokter atau apoteker Anda jika Anda sedang minum, baru saja minum atau mungkin mengonsumsi obat lain. Ini sangat penting karena meminum lebih dari satu obat pada saat bersamaan dapat memperkuat atau melemahkan efeknya.

GYNPROGEST dengan makanan dan minuman

Minum obat saat makan meningkatkan penyerapannya sehingga Anda harus tetap melakukan rutinitas yang sama untuk meminumnya dalam kaitannya dengan makan (misalnya: setiap hari setelah makan malam sebelum tidur), hindari variasi dari satu hari ke hari lainnya.

Kehamilan dan menyusui

Jika Anda sedang hamil atau menyusui, mengira Anda mungkin hamil atau berencana untuk memiliki bayi, tanyakan kepada dokter atau apoteker untuk nasihat sebelum minum obat ini.

- Kehamilan

Progesteron adalah hormon yang meningkat selama kehamilan dan pemberian selama periode ini karenanya tidak menimbulkan efek samping.

- Menyusui

Progesteron diekskresikan dalam ASI. Oleh karena itu, pemberian tidak dianjurkan pada wanita yang sedang menyusui.

Mengemudi dan menggunakan mesin.

Karena risiko kantuk dan / atau pusing telah dilaporkan sehubungan dengan penggunaan progesteron secara oral, Anda harus menghindari situasi yang mengharuskan Anda sangat waspada, seperti mengemudi kendaraan atau menggunakan mesin.

3. Cara mengambil / menggunakan GYNPROGEST

Selalu minum obat ini persis seperti yang dijelaskan dalam selebaran ini atau seperti yang dikatakan dokter atau apoteker Anda. Periksa dengan dokter atau apoteker Anda jika Anda tidak yakin.

Ingatlah untuk minum obat Anda.

Dokter Anda akan memberi tahu Anda berapa lama untuk mengambil perawatan GYNPROGEST. Jangan hentikan perawatan sebelum selesai.

Dosis bervariasi sesuai dengan alasan pengobatan; ikuti instruksi dokter Anda dengan ketat.

Dosis normalnya adalah:

Pemberian oral: Umumnya, dosisnya adalah 200 sampai 300 mg progesteron (2 sampai 3 kapsul) per hari.

Pemberian vagina: Dosis dapat berkisar dari 100 hingga 600 mg / hari (1 hingga 6 kapsul), tergantung pada alasan pengobatan.

Jika Anda mengambil lebih banyak GYNPROGEST dari yang seharusnya
Jika terjadi overdosis atau asupan yang tidak disengaja, segera hubungi dokter atau apoteker Anda, sebutkan obat dan jumlah yang diminum.

Jika Anda lupa mengambil / menggunakan GYNPROGEST
Minumlah secepat mungkin dan lanjutkan perawatan seperti biasa.
Jangan mengambil dosis ganda untuk mengganti dosis yang terlupakan.

Jika Anda menghentikan perawatan dengan GYNPROGEST
Jika Anda memiliki pertanyaan lebih lanjut tentang penggunaan produk ini, tanyakan kepada dokter atau apoteker Anda.

4. Interaksi obat

Gynprogest dapat mengganggu efek bromocriptine dan dapat meningkatkan konsentrasi plasma cyclosporine. Gynprogest dapat mempengaruhi hasil tes laboratorium fungsi hati dan/atau endokrin.
Metabolisme Gynprogest dipercepat oleh rifampicin sebagai agen antibakteri. Metabolisme progesteron oleh mikrosom hati manusia dihambat oleh ketoconazole ($IC_{50} < 0,1 \text{ m}$). Ketoconazole dikenal sebagai penghambat sitokrom P450 3A4. Oleh karena itu ketoconazole dapat meningkatkan bioavailabilitas progesteron.

5. Kemungkinan efek samping

Seperti semua obat-obatan, GYNPROGEST dapat menyebabkan efek samping, meskipun tidak semua orang mengalaminya.
Efek samping berikut dapat terjadi:

Pemberian oral:

Mengantuk dan / atau episode pusing yang bisa terjadi 1 sampai 3 jam setelah minum obat. Memperpendek durasi siklus menstruasi atau perdarahan terobosan pada defek fase luteal.

Jika salah satu efek samping menjadi serius, atau jika Anda melihat ada efek samping yang tidak tercantum dalam brosur ini, silakan beritahu dokter atau apoteker Anda atau menghubungi bagian Farmakovigilans kami (email: pv.indonesia@exeltis.com ; Phone: +62-822-2517-7979).

6. Bagaimana cara menyimpan GYNPROGEST

Jauhkan obat ini dari pandangan dan jangkauan anak-anak. Simpan dalam kemasan aslinya.

Jangan gunakan obat ini setelah tanggal kadaluwarsa yang tertera pada wadah setelah Kedaluwarsa. Tanggal kadaluwarsa mengacu pada hari terakhir bulan itu.

Jangan membuang obat apa pun melalui air limbah atau limbah rumah tangga. Tinggalkan bungkus dan obat-obatan yang tidak lagi Anda butuhkan di apotek. Jika Anda tidak yakin, tanyakan kepada apoteker Anda bagaimana cara membuang obat yang tidak lagi Anda gunakan. Tindakan ini akan membantu melindungi lingkungan.

7. Isi paket dan informasi lain

40 mm

7. Isi paket dan informasi lain

Komposisi GYNPROGEST

Bahan aktifnya adalah progesteron termikronisasi, 100 mg per kapsul gelatin lunak. Bahan lainnya adalah:

Isi: minyak kacang tanah dan lesitin kedelai.

Cangkang: gelatin, gliserol, titanium dioksida.

Seperti apa produk itu dan isi kemasannya

GYNPROGEST adalah kapsul gelatin lembut untuk penggunaan oral atau vagina. Tersedia dalam kemasan berisi 15 dan 30 kapsul

No. Izin Edar

Gynprogest 100 mg : Box, 2 blisters @ 15 soft capsules

Reg.No.DKI2238100702A1

Gynprogest 200 mg : Box, 1 blister @ 15 soft capsules

Reg.No.DKI2238100702B1

Diimpor oleh:

PT. NUFARINDO

Semarang - Indonesia

Diproduksi oleh:

Laboratorios Leon Farma S.A

Spain

HARUS DENGAN RESEP DOKTER

R1-xxxx



10 mm

202 mm

222 mm