165mm

155mm

OVERDOSAGE
The available data with regard to overdose in humans are limited.
Dydrogesterone has been well tolerated after oral administration (maximum daily dose in humans to date has been 360 mg). No specific antidotes are known. Treatment should be symptomatic. This information also applies to overdoses in children.

HOW SUPPLIED
Dynagest 10mg tablet is available in blister packs of 1x10's, 2x10's, 3x10's & 4x10's

DOSAGE:
As directed by the physician.

Instructions:
Store below 30˚C in a dry place, protect from light.
To be dispensed on the prescription of a registered medical practitioner only.
Keep out of the reach of children.

خوراک : ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایات : دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر روشنی سے بچا کر خشک جگہ پر رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے پر ہی فروخت کریں۔
بچوں کی پہنچ سے دور رکھیں۔

Note: Product contains lactose.

نوٹ: پروڈکٹ میں لیکٹوز شامل ہے۔

Manufactured by:
Platinum Pharmaceuticals (Pvt.) Ltd.
A-20, North Western Industrial Zone, Bin Qasim,
Karachi - 75020, Pakistan.
Manufactured for Kaizen Pharmaceuticals (Pvt.) Ltd.

Art no. 1526

Dynagest

(Dydrogesterone)

10mg Tablets

ڈائناجیسٹ

(ڈائیڈروجیسٹیرون)

۱۰ ملی گرام گولیاں

Composition:
Each film coated tablet contains:
Dydrogesterone…….....10mg

CLINICAL PHARMACOLOGY
Pharmacodynamics:
Mechanism of Action:
Dydrogesterone is a selective progestin that binds specifically to progesterone receptors. Unlike older synthetic progestogens, it:
- Acts directly on the endometrium without suppressing ovulation
- Maintains a secretory endometrium to support implantation
- Counterbalances estrogen in hormone replacement therapy (HRT

Due to its lack of androgenic, estrogenic, and corticoid effects, dydrogesterone tablets are safe for long-term reproductive use.

PHARMACOKINETICS
After oral administration of labeled dydrogesterone on average 63% of the dose is excreted into the urine. Within 72 hours excretion is complete. Dydrogesterone is completely metabolized. The main metabolite of dydrogesterone is 20α-dihydrogesterone (DHD) and is present in the urine predominantly as the glucuronic acid conjugate. A common feature of all metabolites characterized is the retention of the 4,6diene-3-one configuration of the parent compound and the absence of 17α-hydroxylation. This explains the lack of estrogenic and androgenic effects of dydrogesterone.
After oral administration of dydrogesterone, plasma concentrations of DHD are substantially higher as compared to the parent drug. The AUC and Cmax ratios of DHD to dydrogesterone are in the order of 40 and 25, respectively.
Dydrogesterone is rapidly absorbed. The Tmax values of dydrogesterone and DHD vary between 0.5 and 2.5 hours.
Mean terminal half-lives of dydrogesterone and DHD vary between 5 to 7 and 14 to 17 hours, respectively. Dydrogesterone is not excreted in urine as pregnanediol, like progesterone. Analysis of endogenous progesterone production based on pregnanediol excretion therefore remains possible.

SPECIAL POPULATION
Pregnancy
Dynagest 10 mg is not authorized for use in pregnancy.
It is estimated that more than 10 million pregnancies have been exposed to dydrogesterone. So far there is no evidence of any harmful effect of dydrogesterone use during pregnancy.
The literature suggests that some progestogens are associated with an increased risk of hypospadias. Due to confounders during pregnancy, no definitive conclusion can be drawn on the actual contribution of these progestogens on the risk of hypospadias. Clinical trials in which a limited number of women in early pregnancy were treated with dydrogesterone showed no increased risk. No other epidemiological data are yet available.

Observed effects in non-clinical embryo-fetal and post-natal development studies were in line with the pharmacological profile. Untoward effects occurred only at exposures which exceeded the maximum human exposure considerably, therefore indicating little relevance to clinical use.

Breastfeeding
There are no data on the excretion of dydrogesterone in mother's milk. Experience with other progestogens indicates that progestogens and their metabolites pass into breast milk in small amounts.
It is not known whether there is any risk to the baby. Therefore, Dynagest 10 mg should not be taken while breastfeeding.

Fertility
There is no evidence that dydrogesterone decreases fertility at therapeutic doses.

THERAPEUTIC INDICATIONS
Dynagest 10mg is used for women with:

Progesterone insufficiencies: Treatment of dysmenorrhoea, endometriosis, irregular menstrual cycles and pre-menstrual syndrome.

Hormone replacement therapy: Dydrogesterone is used to supplement an estrogen treatment in non-hysterectomised women with symptoms due to natural onset of or surgically induced menopause. In the context of hormone replacement therapy, it counteracts the estrogen influence on the endometrium.

Dysfunctional bleeding or secondary amenorrhoea: The drug may be used with an estrogen in the management of these conditions.

DOSAGE & ADMINISTRATION
The dosage, regimen and duration of treatment should be adjusted according to the severity of the symptoms and the clinical response.

Progesterone insufficiencies:
Dysmenorrhoea:
10 mg of dydrogesterone twice a day from day 5 to 25 of the cycle.

Endometriosis:
10 mg of dydrogesterone two to three times daily from day 5 to 25 of the cycle, or continuously.

Irregular menstrual cycles:
10 mg of dydrogesterone twice a day from day 11 to 25 of the cycle.

Pre-menstrual syndrome:
10 mg of dydrogesterone twice a day from day 12 to 26 of the cycle. The dosage may be increased if necessary.

Hormone replacement therapy: i.e. as supplement in estrogen treatment in nonhysterectomised women with symptoms due to natural onset of or surgically induced menopause:

• Continuous sequential therapy: continuous use of an estrogen; sequential supplementation of 10 mg dydrogesterone during the last 14 days of each 28-day cycle
• Cyclical treatment: cyclic use of an estrogen with a treatment-free period, usually 21 days on and 7 days off treatment. For the last 12-14 days of estrogen use, 10 mg of dydrogesterone is supplemented.
• Depending on the clinical response, the dosage may be adjusted to 20 mg dydrogesterone daily in the course of the treatment.

Dysfunctional uterine bleeding:
When treatment is started to arrest a bleeding episode 10 mg of dydrogesterone twice a day for five to seven days.
For continuous treatment 10 mg of dydrogesterone twice a day from day 11 to day 25 of the cycle.
Withdrawal bleeding occurs if the endometrium has been adequately primed with either endogenous or exogenous estrogen.

Secondary amenorrhoea:
10 mg of dydrogesterone twice a day from day 11 to 25 to produce an optimum secretory transformation of an endometrium that has been adequately primed with either endogenous or exogenous estrogen.

METHOD OF ADMINISTRATION
For oral administration.

ADVERSE REACTIONS
Like all medicines Dydrogesterone solution can cause side effects, although not everybody gets them.

Side effects are:
Mild stomach upsets such as stomach cramps and diarrhea, or you may feel or be sick for a short time.
For people also taking anticoagulant medicine, such as warfarin, tests may show your blood is taking longer than usual to clot.
Drug-related body odor. Your doctor may reduce your dose to help lessen or stop the odor.

CONTRAINDICATIONS
- Hypersensitivity to the active substance or to any of the excipients.
- Known or suspected progestogen-dependent tumors (e.g., meningioma)
- Unexplained vaginal bleeding.
- Contraindications for the use of estrogens should be taken into account when used in combination with dydrogesterone.
- Severe acute and chronic liver diseases as well as disorders in the metabolism of bile pigments (e.g., Dubin-Johnson syndrome, Rotor syndrome).
- Previous or existing liver tumors.
- Thrombophlebitis and thromboembolic diseases.

PRECAUTIONS
• Use under medical guidance in pregnancy and lactation.
• Monitor in patients with liver disorders.
• Discontinue if jaundice or significant bleeding occurs.

DRUG INTERACTIONS
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines
• obtained without a prescription or herbal medicines.
• In particular, tell your doctor or pharmacist if you are taking any of the following:
• These medicines may lower the effect of Duphaston and lead to bleeding or spotting
• medicines for fits (epilepsy) such as phenobarbital, phenytoin or carbamazepine
• medicines for infection such as rifampicin, rifabutin, nevirapine, efavirenz
• medicines for HIV infection (AIDS) such as ritonavir or nelfinavir
• herbal medicines containing St John's Wort (Hypericum perforatum), sage, or ginkgo biloba
• If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Duphaston.