

Dydrogest

Dydrogesterone USP



Composition

Dydrogest Tablet: Each film coated tablet contains Dydrogesterone USP 10 mg.

Description

Dydrogesterone is an orally active, synthetic progestogen which produces a complete secretory endometrium in an oestrogen-primed uterus. At therapeutic levels, dydrogesterone has no contraceptive effect as it does not inhibit or interfere with ovulation or the corpus luteum. Furthermore, dydrogesterone is non-androgenic, non-estrogenic, non corticoid, non-anabolic and is not excreted as pregnanediol. Dydrogesterone helps to regulate the healthy growth and normal shedding of the uterus lining.

Indications and usage progesterone deficiencies

Dydrogest is indicated for the treatment of dysmenorrhoea, endometriosis, secondary amenorrhoea, irregular cycles, dysfunctional uterine bleeding, pre-menstrual syndrome, threatened and habitual abortion associated with proven progesterone deficiency and infertility due to luteal insufficiency.

Hormone replacement therapy

Dydrogest is indicated for hormone replacement therapy in women with disorders due to naturally or surgically induced menopause in women with an intact uterus.

Dosage and administration

Always take Dydrogest as your doctor has prescribed. If you forget to take your tablet(s).

Do not make a double dose to compensate for it.

Progesterone deficiencies

Infertility due to luteal insufficiency: Take one tablet daily from day 14 to 25 of the cycle. Continue the treatment for at least six consecutive cycles, it is advisable to continue treatment for the first few months of pregnancy as described under "Habitual Abortion.

Habitual abortion: Take one tablet twice daily until the twentieth week of pregnancy.

Threatened abortion: Take four tablets at once, then one tablet every eight hours until symptoms abate. **Irregular cycles:** Take one tablet daily from day 11 to day 25 of the cycle.

Amenorrhea: A estrogen along with Dydrogest should be prescribed. Then take the estrogen once daily from day 1 to day 25 of the cycle, together with one tablet of dydrogesterone twice daily. **Pre-menstrual syndrome:** Take one tablet twice daily from day 11 to day 25 of the cycle.

Dysmenorrhea: Take one tablet twice daily from day 5 to day 25 of the cycle **Endometriosis:** Take one tablet two or three times daily from day 5 to day 25 of the cycle or continuously. **Dysfunctional uterine bleeding:** To stop bleeding, take one tablet twice daily for five to seven days. To prevent bleeding take one tablet twice daily from day 11 to day 25 of the cycle.

Hormone Replacement Therapy

1. In combination with continuous estrogen therapy, take one tablet daily for 14 consecutive days of a 28 days cycle.
2. In combination with cyclical estrogen therapy, take one tablet daily during the last 12 to 14 days of estrogen therapy.
3. If endometrial biopsies or ultrasound reveal inadequate progesterone response, 20 mg (2 tablets) dydrogesterone should be prescribed. Dydrogest is not recommended for use in children below age 18 due to insufficient data on safety and efficacy.

Side Effects

The most commonly reported adverse drug reactions of patients treated with dydrogesterone are headache, nausea, menstrual disorders and breast pain/tenderness.

Precautions

Before initiating dydrogesterone treatment for abnormal bleeding the etiology for the bleeding should be clarified. Breakthrough bleeding and spotting may occur during the first months of treatment. If breakthrough bleeding or spotting appears after some time on therapy, or continues after treatment has been discontinued, the reason should be investigated, which may include endometrial biopsy to exclude endometrial malignancy. If one of the following disorders occurs during use for the first time or gets worse, stopping the treatment should be considered.

1. Severe headache, migraine or symptoms that may indicate cerebral ischemia.
2. Marked increase in blood pressure.
3. Occurrence of venous thromboembolism (VTE) In cases of habitual or threatened abortion, the viability of the foetus should be ascertained. It is also necessary to monitor during treatment whether the pregnancy is still progressing and whether the embryo is still alive. Patients with a history of depression must be carefully monitored; if severe depression recurs, treatment with dydrogesterone must be stopped

Contraindications

- Hypersensitivity to the active substance or to any of the excipients.
- Known or suspected progestogen dependent neoplasms (e.g. meningioma)
- Undiagnosed vaginal bleeding
- If used to prevent endometrial hyperplasia (in women using estrogens): Contraindications for use of estrogens in combination with progestagens, such as Dydrogesterone.

Drug Interactions

Drugs that induce CYP enzymes such as anti-convulsants (e.g., phenobarbital, phenytoin, carbamazepine), anti-infectives (e.g., rifampicin, rifabutin, nevirapine, efavirenz) and herbal preparations containing St John's wort, valerian root, sage or ginkgo biloba may lead to a decreased effect of Dydrogesterone and its active metabolite dihydrodydrogesterone (DHD).

Use in Pregnancy & Lactation Pregnancy

Pregnancy: There were no harmful effects found in patients using dydrogesterone during pregnancy.

Lactation: No data exist on excretion of dydrogesterone in mother's milk. Experience with other progestogens indicates that progestogens and the metabolites pass to mother's milk in small quantities. Therefore, dydrogesterone should not be used during the lactation period.

Use in Children

There is no relevant use of dydrogesterone in children. The safety and efficacy of dydrogesterone in adolescents has not been established.

Overdosage

Dydrogesterone was well tolerated after oral dosing (maximum daily dose is 360 mg). No reports of ill-effects from overdose have been recorded. There are no specific antidotes and treatment should be symptomatic.

Storage

Do not store above 30°C. Protect from light. Keep out of reach of children.

Packaging:

Dydrogest Tablet: Each box contains 3x10's tablets in blister pack

Manufactured by



Ziska Pharmaceuticals Ltd.
Kaliakoir, Gazipur, Bangladesh

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