

Dydrogesterone BP

Composition

Each tablet contains Dydrogesterone BP 10 mg.

Pharmacology

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

Progesterone Deficiencies: D-gest (Dydrogesterone) 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: D-gest is indicated for hormone replacement therapy in women with disorders due to naturally or surgically induced menopause in women with an intact uterus.

Dosage & Administration

Always take D-gest 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 D-gest 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

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

Contraindications

- Hypersensitive to the active substance or to any of the excipients.
- Have a known or suspected progesterone dependent neoplasm.
- Have undiagnosed vaginal bleeding
- Are using this medicine to prevent endometrial hyperplasia (abnormal growth of the uterus), Specifically if patient is also taking estrogen : progestogen such as Dydrogesterone is contraindicated in combination with estrogen.

Warning & 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.

- Severe headache, migraine or symptoms that may indicate cerebral ischemia.
- Marked increase in blood pressure.
- 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

Side Effects

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

Use in Pregnancy & Lactation

Pregnancy: There were no harmful effects found in patients using D-gest (Dydrogesterone) during pregnancy.

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

Use in Children & Adolescents

There is no relevant use of D-gest (Dydrogesterone) in children. The safety and efficacy of Dydrogesterone in adolescents has not been established.

Drug Interaction

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).

Over Dose

Dydrogesterone was well tolerated after oral dosing (maximum daily dose is 360 mg). No reports of ill-effects from overdose have been recorded. If a large overdose is discovered within two or three hours and treatment seems desirable, gastric lavage is recommended. There are no specific antidotes and treatment should be symptomatic.

Storage

Store below 30° C temperature & dry place, protected from light. Keep all medicine out of reach of all children.

Commercial Pack

Each box contains 3x10 tablets in blister strips.

* Further information is available on request.



Manufactured by:
The ACME Laboratories Ltd.
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For Health, Vigour and Happiness