

Safyron™

Dydrogesterone Ph. Eur. 10 mg

Composition

Each film coated tablet contains Dydrogesterone Ph. Eur. 10 mg.

Description

Safyron™ (Dydrogesterone) is a synthetic progestogen and has a similar action to the female hormone, progesterone. It is used to treat menstrual disorders in women caused due to a lack of hormones. It is also used to reduce the risk of miscarriages or abortions.

Mechanism of action

Safyron™ (Dydrogesterone) is an orally active progestogen which acts directly on the uterus, producing a complete secretory endometrium in an estrogen-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. Therefore, it may be useful in the treatment of menstrual disorders such as absent, irregular or painful menstrual periods, infertility, premenstrual syndrome and endometriosis.

Pharmacokinetics

Absorption: Rapidly absorbed in the gastrointestinal tract with a bioavailability of 28%.

Distribution: After intravenous administration of Dydrogesterone the steady-state distribution volume is around 1400 L. More than 90% of Dydrogesterone and DHD are bound to plasma-proteins.

Metabolism: Metabolism is complete to a 20-dihydrodydrogesterone (DHD) metabolite.

Elimination: After oral administration of labelled Dydrogesterone on average 63% of the dose is excreted in the urine. The total plasma clearance is 6.41/minute. Within 72 hours the excretion is complete, DHD is present in the urine mainly as the conjugated glucuronic acid.

Indication

Progesterone deficiencies:

- Treatment of threatened miscarriage
- Treatment of habitual miscarriage
- Treatment of dysmenorrhoea
- Treatment of endometriosis
- Treatment of secondary amenorrhoea
- Treatment of irregular cycles
- Treatment of dysfunctional uterine bleeding
- Treatment of infertility due to luteal insufficiency
- Luteal support as part of an Assisted Reproductive Technology (ART)

Hormone Replacement Therapy:

To counteract the effects of unopposed oestrogen on the endometrium in hormone replacement therapy for women with disorders due to natural or surgical induced menopause with an intact uterus.

Limitation of Use

Safyron™ is not recommended for use in children below age 18 due to insufficient data on safety and efficacy.

Dosage & Administration

For oral use only.

For hormone replacement therapy:

- In combination with continuous estrogen therapy, take one tablet daily for 14 consecutive days of a 28 day cycle.
- In combination with cyclical estrogen therapy, take one tablet daily during the last 12 to 14 days of estrogen therapy.
- For doctors: If endometrial biopsies or ultrasound reveal inadequate progesterational response, 20 mg Dydrogesterone should be prescribed.

Others bleeding and progesterone deficiency:

- Dysmenorrhoea (painful menstruation)

Take one tablet twice daily from day 5 to day 25 of the cycle.

- Endometriosis (abnormal growth of uterine tissues outside the uterus)

Take one tablet two or three times daily from day 5 to day 25 of the cycle or continuously (as prescribed by your doctor).

- Dysfunctional bleeding (to stop bleeding)

Take one tablet twice daily for five to seven days.

- Dysfunctional bleeding (to prevent bleeding)

Take one tablet twice daily from day 11 to day 25 of the cycle.

- Amenorrhoea (cessation of menstruation)

Your doctor should prescribe an estrogen along with **Safyron™**. Then take the estrogen once daily from day 1 to day 25 of the cycle, together with one tablet of Dydrogesterone twice daily from day 11 to day 25 of the cycle.

- Premenstrual syndrome

Take one tablet twice daily from day 11 to day 25 of the cycle.

- Irregular cycles

Take one tablet twice daily from day 11 to day 25 of the cycle.

- Threatened abortion

Take four tablets at once, then one tablet every eight hours until symptoms abate.

- Habitual abortion

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

- Infertility due to luteal (yellow body) insufficiency

Take one tablet daily from day 14 to 25 of the cycle. Continue the treatment for at least six consecutive cycles. In addition, it is advisable to continue treatment for the first few months of pregnancy as described under 'Habitual abortion'. If you are uncertain about how long to continue the treatment, talk to your doctor.

Contraindications

Do not take **Safyron™** if you

- are hypersensitive (allergic) 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 lining of the uterus), specifically if patient is also taking estrogens: See Contraindications for use of estrogens in combination with progestogens, such as Dydrogesterone.

Overdosage

There are no known cases where an overdose of Dydrogesterone has resulted in harmful consequences.

Special Precautions

Before initiating Dydrogesterone treatment for dysfunctional uterine bleeding an organic cause must be ruled out. 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 should be discontinued & reason should be investigated, if necessary by endometrial biopsy to exclude endometrial malignancy.

Adverse Reactions

The most commonly reported adverse drug reactions of patients treated with Dydrogesterone in clinical trials of indications without oestrogen treatment are migraines / headache, nausea, menstrual disorders and breast pain/tenderness.

Pregnancy and Lactation

It is estimated that altogether roughly 35 million women have been treated with Dydrogesterone. From spontaneous surveillance systems to date, there is no evidence that Dydrogesterone cannot be used during pregnancy. No other relevant epidemiological data on Dydrogesterone are available.

There is no evidence that Dydrogesterone decreases fertility. Dydrogesterone is excreted in the milk of nursing mothers. A risk to the suckling child cannot be excluded. Dydrogesterone should not be used during breast-feeding.

Storage

Store below 30° C. Protect from light & moisture. Keep all medicines out of reach of children.

How supplied

Safyron™ Tablet: Each box contains 20's tablets in blister packs.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH