DYDROPREG

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for DYDROPREG

(Dydrogesterone Tablets I.P. 10 mg)

[Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES:

Mechanism of Action: Dydrogesterone is an orally-active progestogen which produces a complete secretory endometrium in an estrogen-primed uterus thereby providing protection against the increased risk for endometrium hyperplasia and/or carcinogenesis induced by estrogens. It is indicated in all cases of endogenous progesterone deficiency.

INDICATIONS: Luteal support as part of an assisted reproductive technology (ART) treatment. **DOSAGE AND ADMINISTRATION: Infertility due to luteal insufficiency:** 10 or 20 mg Dydrogesterone daily starting with the second half of the menstrual cycle until the first day of the next cycle. Treatment should be maintained for at least three consecutive cycles.

CONTRAINDICATION: 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 oestrogens in combination with progestagens, such as Dydrogesterone.

WARNINGS & 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.

DRUG INTERACTIONS: In vitro data show that the major metabolic pathway generating the main pharmacologically active metabolite 20α Dihydrodydrogesterone (DHD) is catalyzed by aldo-keto reductase 1C (AKR 1C) in human cytosol. Next to the cytosolic metabolism there are metabolic transformations by cytochrome P450 iso-enzymes (CYPs), nearly exclusively via CYP3A4, resulting in several minor metabolites. The main active metabolite DHD is substrate for metabolic transformation by CYP3A4. Therefore, the metabolism of Dydrogesterone and DHD may be increased by concomitant use of substances known to induce CYP enzymes such as anticonvulsants (e.g., Phenobarbital, Phenytoin, and Carbamazepine), anti-infectives (e.g., Rifampicin, Rifabutin, Nevirapine, Efavirenz) and herbal preparations containing e.g. St John's Wort (Hypericumperforatum), sage, or gingko biloba. Ritonavir and nelfinavir, although known as strong cytochrome enzyme inhibitors, by contrast exhibit enzyme-inducing properties when used concomitantly with steroid hormones. Clinically, an increased metabolism of Dydrogesterone may lead to a decreased effect. In vitro studies have shown that Dydrogesterone and DHD do not inhibit or induce CYP drug metabolizing enzymes at clinically relevant concentrations.

ADVERSE REACTIONS: Depression, Hypersensitivity, Migraine, Headache, Dizziness, Somnolence, Nausea and Vomiting, Disturbed liver function (with Icterus, Asthenia or Malaise, and abdominal pain), Allergic dermatitis (e.g. rash, Angiooedema*), Disturbed menstruation (including Metrorrhagia, menorrhagia, Oligo- /amenorrhoea, Dysmenorrhoea and Irregular menstruation) Painful/ sensitive breasts, Swelling of the breasts, Oedema and weight gain.

MARKETED BY:

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