Provenor®

Medroxyprogesterone Acetate USP Tablet

DESCRIPTION

Provenor® is a preparation of Medroxyprogesterone Acetate. Medroxyprogesterone Acetate is a progestogen and a derivative of progesterone. When administered in recommended doses to women with adequate endogenous oestrogen, it transforms proliferative into secretory endometrium. Medroxyprogesterone Acetate may inhibit gonadotrophin production, which in turn prevents follicular maturation and ovulation. Like progesterone, Medroxyprogesterone Acetate is thermogenic. At the very high dosage levels used in the treatment of certain cancers, corticoid-like activity may be manifest.

INDICATIONS

Low dosage (**Provenor® 5** and **Provenor® 10**) is indicated for:

- Diagnosis of primary and secondary amenorrhoea
- Treatment of dysfunctional (anovulatory) uterine bleeding
- Opposition of endometrial effects of oestrogen in menopausal women being treated with oestrogen (hormone replacement therapy [HRT])
- Treatment of endometriosis

High dosage (100 mg and 200 mg tablets): is indicated as adjunctive and/or palliative treatment of recurrent and/or metastatic endometrial or renal carcinoma and, in the treatment of hormonally-dependent, recurrent breast cancer in post-menopausal women.

DOSAGE AND ADMINISTRATION

Use of combined oestrogren/progestin therapy in postmenopausal women should be limited to the lowest effective dose and the shortest duration consistent with treatment goals and risks for the individual woman, and should be periodically evaluated.

Unless there is a previous diagnosis of endometriosis, it is not recommended to add a progestin in a woman without an intact uterus.

Diagnosis of Primary and Secondary Amenorrhoea: 2.5 to 10 mg per day for 5-10 days.

Dysfunctional (anovulatory) Uterine Bleeding: 2.5 to 10 mg per day for 5 to 10 days for 2 to 3 cycles and then discontinued to see if the dysfunction has regressed. If bleeding occurs from a poorly proliferative endometrium, oestrogens should be used concomitantly with Medroxyprogesterone Acetate therapy.

Opposition of Endometrial Effects of Oestrogen in Menopausal Women Being Treated with Oestrogen: For women taking 0.625 mg of conjugated oestrogen or an equivalent daily dose of another oestrogen; **Provenor®** can be given in one or two regimens:

Continuous regimen of Medroxyprogesterone Acetate: 2.5 to 5.0 mg daily.

Sequential regimen of Medroxyprogesterone Acetate: 5 to 10 mg daily for 10 to 14 consecutive days of a 28-day or monthly cycle.

Endometriosis: 10 mg three times a day for 90 consecutive days, beginning on the first day of the menstrual cycle.

Endometrial and renal carcinoma: Doses of 100-600 mg per day of Medroxyprogesterone Acetate are recommended.

Breast cancer: Doses of 400-1500 mg per day are recommended. The patient should then be continued on therapy as long as she is responding to treatment.

NOTE:

Response to hormonal therapy for endometrial, renal or breast cancer may not be evident until after 8 - 10 weeks of therapy. In the event of a rapid progression of disease at any time during therapy, treatment with Medroxyprogesterone Acetate should be terminated. Medroxyprogesterone Acetate is not recommended as primary therapy, but as adjunctive and palliative treatment in advanced, inoperable cases including those with recurrent or metastatic disease.

CONTRAINDICATIONS

- Thrombophlebitis, thrombotic or thromboembolic disorders, cerebral apoplexy or patients with a past history of these conditions.
- Markedly impaired liver function.
- Undiagnosed vaginal bleeding.
- Undiagnosed urinary tract bleeding.
- Undiagnosed breast pathology.
- Missed abortion.
- Known sensitivity to Medroxyprogesterone Acetate.
- Known or suspected pregnancy.

WARNINGS AND PRECAUTIONS

- The physician should be alert to the earliest manifestations of thrombotic disorders (thrombophlebitis, cerebrovascular disorders, pulmonary embolism, and retinal thrombosis). Should any of these occur, the drug should be discontinued immediately.
- Discontinue medication pending examination if there is sudden partial or complete loss of vision, or if there is a sudden onset of proptosis, diplopia or migraine. If examination reveals papilloedema, or retinal vascular lesions, medication should be withdrawn.
- The pretreatment physical examination should include special reference to breast and pelvic organs, as well as Papanicolaou smear. This evaluation should exclude the presence of genital or breast neoplasia unless the patient is to be treated with Medroxyprogesterone for recurrent endometrial, breast or renal cancer.
- Because this drug may cause some degree of fluid retention, conditions which might be influenced by this factor, such as epilepsy, migraine, asthma, or cardiac or renal dysfunction, require careful observation.

USE IN PREGNANCY AND LACTATION

Pregnancy category D. If Medroxyprogesterone Acetate is used during pregnancy, or if the patient becomes pregnant while using Medroxyprogesterone Acetate, the patient should be apprised of the potential risk to the fetus.

ADVERSE REACTIONS

Allergy: Hypersensitivity reactions
Cardiovascular: Cerebral and myocardial infarction, congestive heart failure, increased blood pressure, palpitations, tachycardia.
Central Nervous System: Confusion, loss of concentration, nervousness, insomnia, fatigue, depression, dizziness, headache, and tremor. Some patients may complain of premenstrual-like depression while on Medroxyprogesterone acetate.
Skin and Mucous Membranes: Urticaria, pruritis, rash, acne, hirsutism, alopecia and sweating.
Genitourinary: Irregular uterine bleeding (increase, decrease), spotting, amenorrhoea, prolonged anovulation.
Gastrointestinal / Hepatobiliary: Nausea, vomiting, constipation, diarrhoea, dry mouth, disturbed liver function, jaundice.
Breast: Tenderness, galactorrhoea, mastodynia. The use of oestrogens and progestogens by post-menopausal women has been associated with an increased risk of breast cancer.
Cervix: cervical erosions, changes in excretions and secretions.
Miscellaneous: Changes in appetite, changes in libido, oedema/fluid retention, hyperpyrexia, weight change, malaise, hypercalcaemia.

PHARMACEUTICAL PRECAUTION

Store in a dry place, away from light. Keep out of reach of children.

PACKAGING

Provenor® 5 tablet : Box containing 2 strips of 15 tablets each. Each tablet contains Medroxyprogesterone Acetate USP 5 mg.

Provenor® 10 tablet : Box containing 2 strips of 15 tablets each . Each tablet contains Medroxyprogesterone Acetate USP 10 mg.

Manufactured for
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BY POPULAR PHARMACEUTICALS LIMITED
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