

NON-PREG[®]
Injection

PRODUCT DESCRIPTION :

It is a sterile white suspension for injection.

COMPOSITION :

Each vial of 3 mL contains :

Medroxyprogesterone Acetate	150 mg
Methylparaben	4.95 mg
Propylparaben	0.54 mg

PHARMACODYNAMICS :

When Medroxyprogesterone Acetate is administered IM at the recommended to women every three months, it inhibits the secretion of gonadotropins, which in turn, prevents follicular maturation and ovulation and results in endometrial thinning. These actions produce its contraceptive effect.

Medroxyprogesterone shares the pharmacologic actions of the progestins. In women with adequate endogenous estrogen, medroxyprogesterone transforms a proliferative endometrium into a secretory one. Although medroxyprogesterone inhibits the secretion of pituitary gonadotropins following IM administration, thus preventing follicular maturation and ovulation, available evidence indicates that these effects do not occur following oral administration of usual dosages (ie., 5-10 mg daily as single daily doses) of the drug. High doses of medroxyprogesterone inhibit pituitary secretion of luteinizing hormone (LH) and follicle-stimulating hormone (FSH), and will prevent cyclic gonadotropin surges that occur during the normal menstrual cycle. It has been suggested that the drug acts at the hypothalamus since it does not suppress the release of LH and FSH following administration of gonadotropin-releasing hormone and since basal concentrations of LH and FSH remain within the low normal range when the drug is used as a contraceptive. Although the mechanism of action has not been determined, medroxyprogesterone has antineoplastic activity against some cancers (e.g., endometrial carcinoma, renal carcinoma.).

Based on results from a French epidemiological case-control study, an association between medroxyprogesterone acetate and meningioma has been observed. This study was based on data from the French National health data system (SNDS-Système National des Données de Santé) and included a population of 18,061 women who had intracranial surgery for meningioma and 90,305 women without meningioma. The exposure to medroxyprogesterone acetate 150 mg/3ml injectable was compared between women who had intracranial surgery for meningioma and women without meningioma. Analyses showed an excess risk of meningioma with the use of medroxyprogesterone acetate 150 mg/3 ml (9/18,061 (0.05%) v 11/90,305 (0.01%), OR 5.55 (95% CI 2.27 to 13.56)). This excess risk seems to be driven primarily by prolonged use (≥3 years) of medroxyprogesterone acetate.

PHARMACOKINETICS :

Following IM administration of Non-Preg[®] injection, the apparent half-life of Medroxyprogesterone Acetate is approximately 50 days. It is absorbed from the gastrointestinal tract. It is hydroxylated in the liver and excreted mainly in the faeces. It is reported to be excreted in the breast milk.

INDICATION :

It is a long-term contraceptive agent and treatment of endometriosis.

ROUTE OF ADMINISTRATION : Intra-muscular (IM)

RECOMMENDED DOSE :

Contraception : 150 mg per 3 mL of Non-Preg[®] once every 3 months.

Endometriosis : 50 mg per 1 mL of Non-Preg[®] once a week or 100 mg per 2 mL of Non-Preg[®] once every 2 weeks.

CONTRAINDICATIONS :

Non-Preg[®] Injection is contraindicated to patients with Thrombophlebitis, Carcinoma of the breast, undiagnosed Vaginal Bleeding, missed abortion, known sensitivity to sterile aqueous suspension of Medroxyprogesterone Acetate, and if use as a diagnostic test for pregnancy.

Patient with meningioma or history of meningioma (for non-oncological indications)

WARNINGS AND PRECAUTIONS :

Warning : It is not recommended during the first four months of pregnancy, or if she becomes pregnant while taking this drug, she should be apprised of the potential risks to the fetus.

General Precautions : Do not take this drug if you have a history of blood clots or similar disorders, a history of convulsions, liver disease, known or suspected breast cancer, undiagnosed vaginal bleeding, or miscarriage. Use of Non-Preg[®] injection should be carefully considered if you have asthma, cardiac insufficiency, epilepsy, migraine headaches, kidney problems, diabetes, a history of ectopic pregnancy, high blood-fat levels, or depression.

Meningioma

Cases of meningioma (single and multiple) have been reported in patients treated with medroxyprogesterone acetate for a prolonged time (several years). Patients treated with medroxyprogesterone acetate should be monitored for signs and symptoms of meningioma in accordance with clinical practice.

In some cases, shrinkage of meningioma was observed after treatment discontinuation of depot medroxyprogesterone acetate. If a patient treated for a non-oncological indication is diagnosed with meningioma, medroxyprogesterone acetate must be stopped, as a precautionary measure.

If a patient treated for an oncological indication is diagnosed with meningioma, the need for further treatment with medroxyprogesterone acetate should be carefully considered on a case-by-case basis taking into account individual benefits and risks.

INTERACTIONS WITH OTHER MEDICAMENTS :

Aminoglutethimide may significantly depress the serum concentrations of Medroxyprogesterone. Warn users of the possibility of decreased efficacy with the use of this or any related drugs.

PREGNANCY AND LACTATION :

Advisability of use during pregnancy: Pregnancy category X. It should never be taken during pregnancy.

Advisability of use if breast feeding (nursing mothers): Presence of this drug in breast milk: Yes.

Avoid its use or refrain from nursing.

SIDE EFFECT :

(See Warnings for possible adverse effects on the fetus).

In a few instances there have been undesirable sequelae at the site of injection, such as residual lump, change in color of skin or sterile abscess.

The following adverse reactions have been associated with the use of Medroxyprogesterone Acetate Sterile Aqueous Suspension.

Breast : In a few instances, breast tenderness or galactorrhea have occurred.

Psychic: An occasional patient has experienced nervousness, insomnia, somnolence, fatigue or dizziness.

Thromboembolic Phenomena: Thromboembolic phenomena including thrombophlebitis and pulmonary embolism have been reported.

Skin and Mucous Membranes: Sensitivity reactions ranging from pruritus, urticaria, angioneurotic edema to generalized rash and anaphylaxis and/or anaphylactoid reactions have occasionally been reported. Acne, alopecia, or hirsutism have been reported in a few cases.

Gastrointestinal: Rarely, nausea has been reported. Jaundice, including neonatal jaundice, has been noted in a few instances.

Miscellaneous : Rare cases of headache and hyperpyrexia have been reported.

The following adverse reactions have been observed in women taking progestins including Medroxyprogesterone Acetate :

Breakthrough bleeding

Spotting

Change in menstrual flow

Amenorrhea

Edema

Change in weight (increase or decrease)

Changes in cervical erosion and cervical secretions

Cholestatic jaundice

Rash (allergic) with and without pruritus

Melasma or chloasma

Mental depression

Neoplasms benign, malignant & unspecified

Frequency (Unknown): meningioma

SYMPTOMS AND TREATMENT OF OVERDOSE :

Non-Preg[®] overdose may result in exaggerated side effects. Treatment is supportive and symptomatic.

STORAGE CONDITION :

Store below 30°C.

SHELF LIFE :

4 years

ATC CODE :

G03AC06 (Medroxyprogesterone)

REG. NO. MAL20020010AZ

BRU NO. BRU20012757P


PACK SIZE :

1 x [10 x 3 mL / vial]

REVISION DATE :

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