Depo-Provera Contraceptive Injection (medroxyprogesterone acetate) - Drug Summary

Pharmacia and Upjohn Company

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Depo-Provera Contraceptive Injection (medroxyprogesterone acetate)

BOXED WARNING

May lose significant bone mineral density (BMD); bone loss is greater w/ increasing duration of use and may not be completely reversible. Unknown if use during adolescence or early adulthood will reduce peak bone mass and increase risk for osteoporotic fractures in later life. Should not be used as long-term birth control (eg, >2 yrs) unless other birth control methods are considered inadequate.

THERAPEUTIC CLASS

Progestin contraceptive

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Contraception

Usual: 150mg deep IM every 3 months (13 weeks)
Dosage does not need to be adjusted for body weight

Conversions

Switching from Other Methods of Contraception:
Give in a manner that ensures continuous contraceptive coverage based upon the mechanism of action of both methods (eg, switching from oral contraceptives should have the 1st inj on the day after the last active tab or at the latest, on the day following the final inactive tab)

PEDIATRIC DOSAGE & INDICATIONS

Contraception

Not indicated for use premenarche; refer to adult dosing

ADMINISTRATION

IM route

Shake vigorously before use
Administer in the gluteal or deltoid muscle
Give the 1st inj only during the first 5 days of a normal menstrual period, only w/in the first 5 days postpartum if not breastfeeding, or only at the 6th postpartum week if exclusively nursing
If the interval between inj is >13 weeks, determine that patient is not pregnant before administering

HOW SUPPLIED

Inj: 150mg/mL [1mL, vial, prefilled syringe]

CONTRAINDICATIONS

Known or suspected pregnancy or as a diagnostic test for pregnancy, active thrombophlebitis, current or past history of thromboembolic disorders, cerebral vascular disease, known or suspected malignancy of the breast, significant liver disease, undiagnosed vaginal bleeding.

WARNINGS/PRECAUTIONS

May pose additional risk of BMD loss in patients w/ risk factors for osteoporosis (eg, chronic alcohol and/or tobacco use, anorexia nervosa, chronic use of drugs that can reduce bone mass [eg, anticonvulsants, corticosteroids]); consider other birth control methods. Serious thrombotic events reported; d/c if thrombosis develops while on therapy unless there are no other acceptable options for birth control. Do not readminister therapy pending examination if there is sudden partial/complete loss of vision, or sudden onset of proptosis/diplopia/migraine; if examination reveals papilledema or retinal vascular lesions, do not readminister. May increase risk of breast cancer; monitor women w/ strong family history of breast cancer carefully. Be alert to possibility of ectopic pregnancy in patients who become pregnant or complain of severe abdominal pain. Anaphylaxis/anaphylactoid reactions reported; institute emergency medical treatment if an anaphylactic reaction occurs. D/C if jaundice or acute/chronic disturbances of liver function develop; do not resume use until markers of liver function return to normal and medroxyprogesterone acetate causation has been excluded. Convulsions and weight gain reported. Monitor patients who have history of depression; do not readminister if depression recurs. May cause disruption of menstrual bleeding patterns (eg, amenorrhea, irregular or unpredictable bleeding/spotting, prolonged spotting/bleeding, heavy bleeding); rule out possibility of organic pathology if abnormal bleeding persists or is severe, and institute appropriate treatment. Decrease in glucose tolerance reported; monitor diabetic patients carefully. May cause fluid retention. Return to ovulation and fertility after discontinuation of therapy may be delayed. Does not protect against HIV infection and other STDs. May change results of some lab tests (eg, coagulation factors, lipids, glucose tolerance, binding proteins).

ADVERSE REACTIONS

BMD loss, menstrual irregularities, increased weight, abdominal pain/discomfort, dizziness, headache, asthenia/fatigue, nervousness, decreased libido, nausea, leg cramps.

DRUG INTERACTIONS

Drugs or herbal products that induce enzymes, including CYP3A4 that metabolize contraceptive hormones (eg, barbiturates, bosentan, St. John's wort) may decrease levels and effectiveness; use additional contraception or a different method of contraception. HIV protease inhibitors and non-nucleoside reverse transcriptase inhibitors may alter levels. Pregnancy reported w/ antibiotics.

PREGNANCY AND LACTATION

Contraindicated in pregnancy, caution in nursing.

MECHANISM OF ACTION

Progestin contraceptive; inhibits secretion of gonadotropins which, in turn, prevents follicular maturation and ovulation, resulting in endometrial thinning.

PHARMACOKINETICS

Absorption: C_{max}=1-7ng/mL, T_{max}=approx 3 weeks. **Distribution:** Plasma protein binding (86%); found in breast milk. **Metabolism:** Liver (extensive) via CYP450 enzymes; reduction, loss of the acetyl group and hydroxylation. **Elimination:** Urine; $T_{1/2}$=approx 50 days.

ASSESSMENT

Assess for active thrombophlebitis, current/past history of thromboembolic disorders or cerebral vascular disease, known or suspected malignancy of the breast, drug hypersensitivity, significant liver disease, undiagnosed vaginal bleeding, osteoporosis risk factors, family history of breast cancer, history of depression, diabetes mellitus (DM), conditions that may be influenced by fluid retention (eg, epilepsy, migraine, asthma, cardiac/renal dysfunction), pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for thrombosis, loss of BMD, breast cancer, sudden/partial loss of vision, proptosis, diplopia, migraine, papilledema, retinal vascular lesions, anaphylaxis/anaphylactoid reactions, jaundice or acute/chronic disturbances in liver function, ectopic pregnancy, convulsions, weight gain, fluid retention, disruption of menstrual bleeding patterns, and other adverse reactions. Monitor patients w/ DM. Monitor for recurrence of depression w/ history of depression. Perform annual exam for a BP check and for other indicated healthcare.

PATIENT COUNSELING

Counsel about the risks/benefits of therapy. Advise at the beginning of treatment that the menstrual cycle may be disrupted and that irregular and unpredictable bleeding or spotting may occur; inform that this usually decreases to the point of amenorrhea as treatment continues w/o other therapy being required. Inform about the possible increased risk of breast cancer in women who use the drug. Inform that drug does not protect against HIV infection and other STDs. Counsel to use a back-up method or alternative method of contraception when enzyme inducers are used w/ the drug. Advise to take adequate Ca^{2+} and vitamin D. Advise to have a yearly visit w/ healthcare provider for a BP check and for other indicated healthcare.

STORAGE

20-25°C (68-77°F). Store vials upright.

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