

MedroxyPROGESTERone Acetate Injectable Suspension, USP

150 mg/mL for intramuscular use

afaxys[®]
pharma

The #1 provider of oral and
emergency contraceptives in U.S. clinics¹

**THIS IS AN INJECTABLE CONTRACEPTIVE IN A
READY-TO-USE, PREFILLED SYRINGE**

COMPARES TO:

Depo-Provera[®]



- Ready to use, available in a prefilled syringe containing 150 mg of medroxyPROGESTERone acetate injectable suspension for use every 3 months (13 weeks)

Packaging Description	NDC #	Dimensions
A Carton Containing 1 Prefilled Syringe	50102-591-40	45 mm x 50 mm x 150 mm

ORDERING INFORMATION
Order from your local drug distributor today

[**ORDER NOW**](#)

ADDITIONAL PRODUCT INFORMATION²:

- An estrogen-free contraceptive.
- Offers effective and discreet pregnancy prevention that does not require daily action.
- Requires re-injection every 3 months (13 weeks), or only 4 times a year, at a healthcare provider.

WARNING: LOSS OF BONE MINERAL DENSITY

Women who use medroxyPROGESTERone acetate injectable suspension may lose significant bone mineral density. Bone loss is greater with increasing duration of use and may not be completely reversible.

It is unknown if use of medroxyPROGESTERone acetate injectable suspension during adolescence or early adulthood, a critical period of bone accretion, will reduce peak bone mass and increase the risk for osteoporotic fracture in later life.

MedroxyPROGESTERone acetate injectable suspension should not be used as a long-term birth control method (i.e., longer than 2 years) unless other birth control methods are considered inadequate.

Limitations of Use: The use of medroxyPROGESTERone acetate injectable suspension is not recommended as a long-term (ie, longer than 2 years) birth control method unless other options are considered inadequate.

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The most common adverse reactions seen in medroxyPROGESTERone acetate injectable suspension, USP (incidence >5%) include: menstrual irregularities (57% at 12 months, 32% at 24 months), abdominal pain/discomfort (11%), weight gain >10 lbs at 24 months (38%), dizziness (6%), headache (17%), nervousness (11%), decreased libido (6%).

MedroxyPROGESTERone acetate injectable suspension does not protect against HIV infection (AIDS) and other sexually transmitted diseases (STDs).

Please see Important Safety Information below.

MedroxyPROGESTERone Acetate Injectable Suspension, USP

150 mg/mL for intramuscular use

Please see accompanying
full Prescribing Information
including Boxed Warning

IMPORTANT SAFETY INFORMATION for medroxyPROGESTERone acetate injectable suspension, USP (150 mg/mL for intramuscular use only)²

INDICATIONS

MedroxyPROGESTERone acetate injectable suspension is indicated only for the prevention of pregnancy.

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Consult the Package Insert or [click here](#) for Complete Prescribing Information

CONTRAINDICATIONS

The use of medroxyPROGESTERone acetate injectable suspension is contraindicated in the following conditions:

- Known or suspected pregnancy or as a diagnostic test for pregnancy
- Active thrombophlebitis, or current or past history of thromboembolic disorders, or cerebral vascular disease
- Known or suspected malignancy of breast
- Known hypersensitivity to medroxyprogesterone acetate injectable suspension or any of its other ingredients
- Significant liver disease
- Undiagnosed vaginal bleeding

WARNINGS AND PRECAUTIONS

- **Loss of bone mineral density**—Use of medroxyPROGESTERone acetate injectable suspension reduces serum estrogen levels and is associated with significant loss of bone mineral density (BMD). This loss of BMD is of particular concern during adolescence and early adulthood, a critical period of bone accretion.
- **Thromboembolic disorders**—Discontinue medroxyPROGESTERone acetate injectable suspension in patients who develop thrombosis unless she has no other acceptable options for birth control.

- **Cancer risks**—Women who have or have had a history of breast cancer should not use hormonal contraceptives, including medroxyPROGESTERone acetate injectable suspension, because breast cancer may be hormonally sensitive. Women with a strong family history of breast cancer should be monitored with particular care.
- **Ectopic pregnancy**—Be alert to the possibility of an ectopic pregnancy among women using medroxyPROGESTERone acetate injectable suspension who become pregnant or complain of severe abdominal pain.
- **Anaphylaxis and anaphylactoid reactions**—Anaphylaxis and anaphylactoid reaction have been reported with the use of medroxyPROGESTERone acetate injectable suspension. Institute emergency medical treatment if an anaphylactic reaction occurs.
- **Liver function**—Discontinue medroxyPROGESTERone acetate injectable suspension if jaundice or disturbances of liver function develop.
- **Other warnings and precautions** include convulsions, carbohydrate and lipid metabolic effects, depression, weight gain, bleeding irregularities including amenorrhea, lactation, interference with laboratory tests.

ADVERSE REACTIONS

The most serious reactions are discussed elsewhere in the labeling and include loss of bone mineral density, thromboembolic disease, breast cancer, and anaphylaxis. Commonly reported adverse reactions include irregular uterine bleeding, abdominal pain/discomfort, weight gain, dizziness, headache, nervousness, and decreased libido.

Patients should be counseled that medroxyPROGESTERone acetate injectable suspension does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

References: 1. Data on File. IQVIA Data. Charleston, SC: Afaxys Pharma, LLC; 2019. 2. MedroxyPROGESTERone acetate injectable suspension prescribing information. Charleston, SC, USA: Afaxys Pharma, LLC; 2020.

To report **SUSPECTED ADVERSE REACTIONS**, call 1-855-888-2467 or report via the FDA MedWatch Program at www.fda.gov/medwatch or 1-800-FDA-1088.

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