DEPO-PROVERA®

Medroxyprogesterone acetate 150 mg/mL injection(depot)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DEPO-PROVERA.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being treated with DEPO-PROVERA against the benefits it is expected to have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What DEPO-PROVERA is used for

The active ingredient of DEPO-PROVERA, medroxyprogesterone acetate, is a chemical similar to the natural hormone progesterone. Progesterone is produced by your ovaries during the second half of your monthly cycle.

There are several reasons why your doctor may have prescribed DEPO-PROVERA for you.

DEPO-PROVERA is used for the following reasons:

Contraception

DEPO-PROVERA is an injectable form of contraception. Each injection protects you from pregnancy for 3 months.

DEPO-PROVERA works by inhibiting the hormones that are needed for the release of the eggs from the ovaries.

Endometriosis

Endometriosis is a condition in which cells from the lining of the uterus (womb) grow in places outside the uterus.

During your period, these cells may grow and break down in the same way as those in the lining of the uterus. This causes pain and discomfort. DEPO-PROVERA helps to stop the growth of the cells found outside the uterus.

Cancer

DEPO-PROVERA is also used in the treatment of certain types of cancer including cancer of the breast, kidney and endometrium (lining of the uterus). It works by inhibiting the growth of these types of cancer cells. DEPO-PROVERA is not a cure for cancer.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

Before treatment with DEPO-PROVERA

When you must not be given it

DEPO-PROVERA should not be given if you have or have had any of the following medical conditions:

- blood clots in your legs
- swelling and redness along a vein (usually extremely tender when touched)
- a stroke
- liver problems
- unusual or irregular vaginal bleeding that has not been diagnosed
- blood in your urine that has not been diagnosed
- known or suspected breast cancer
- any lumps in your breasts that have not been diagnosed
- any bleeding or discharge from your nipples
- miscarriage
- severe, uncontrolled high blood pressure.

Do not use DEPO-PROVERA if you have an allergy to any medicine containing medroxyprogesterone acetate or any of the ingredients listed at the end of this leaflet.

Do not use this medicine if you are pregnant.

DEPO-PROVERA is not suitable for use before menstruation (periods) begins.

Do not breast-feed if you are taking this medicine.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you are not sure whether you should be treated with this medicine, talk to your doctor.

Before treatment with DEPO-PROVERA

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or intend to become pregnant.

Tell your doctor if you are breast-feeding or plan to breast-feed.

Tell your doctor if you have or have had any of the following medical conditions:

- blood clots in your legs
- clotting disorders
- sudden partial or complete loss of vision
- swollen red veins
- abnormal menstrual periods including unusual or irregular bleeding or spotting
- stroke
- cancer including breast cancer or a family history of breast cancer
- bone disease or a family history of bone disease, such as brittle bones (osteoporosis)
- any problems with your breasts
- blood pressure problems
- epilepsy
- migraine
- asthma
- heart problems
- kidney problems
- liver problems
- diabetes
- depression
- any condition that may affect your bone mass e.g., excessive alcohol intake, smoking, anorexia, bone disease or long term treatment with either corticosteroids or medicines for epilepsy.

If you have not told your doctor about any of the above, tell him/her before you start treatment with DEPO-PROVERA.

DEPO-PROVERA is intended to prevent pregnancy. It will not protect you from sexually transmitted diseases such as AIDS (HIV), Hepatitis B and C, genital herpes, genital warts, syphilis or gonorrhoea.

Clinical studies suggest if you are under 35 years of age when you first start treatment with DEPO-PROVERA, you may have a slightly increased risk of developing breast cancer. This is similar to the risk with oral contraceptives (the Pill). If you have any concerns about this, please discuss them with your doctor.

Using DEPO-PROVERA may result in a decrease in the amount of calcium stored in your bones. This could increase your risk of developing brittle bones (osteoporosis), which can lead to bone breakages in later life. This affects women of all ages. However, it can be greater if you are under 18 years old. Your doctor will assess this risk before giving you DEPO-PROVERA and if you continue using DEPO-PROVERA for more than 2 years. If you are under 18 years old, the amount of calcium in your bones will start to recover to its original level once you stop treatment with DEPO-PROVERA. If you are over 18 years old, the calcium levels in your bones may only partially recover to its original level.

Talk to your doctor if you have any concerns over the risk of developing osteoporosis.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

Some medicines may be affected by DEPO-PROVERA or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

Tell your doctor or pharmacist if you are taking aminoglutethimide, a medicine used to treat breast cancer.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How DEPO-PROVERA is given

DEPO-PROVERA is given as an injection into the muscle of your upper arm or buttock. Your doctor or a trained nurse will give you the injection.

The dose and the treatment period for DEPO-PROVERA will depend on the condition for which you have been prescribed this medicine.

Contraception

The recommended dose for effective contraception is 150 mg every three months.

If you are using DEPO-PROVERA as a contraception for the first time, your doctor or trained nurse will advise you on the changes to expect when you start treatment.

It is important that you make arrangements to return to your doctor every three months, for your injection, to ensure that pregnancy is prevented.

If you are using DEPO-PROVERA as a contraceptive for the first time, your first injection should be given during the first 5 days after the start of your normal monthly period.

If you are using DEPO-PROVERA as a form of contraception after the birth of your baby and you are not breast-feeding, the first injection should be given within 5 days after the baby is born.

If you are breast-feeding the first injection should be given 6 weeks

after the baby was born, after your doctor has checked that you are not pregnant.

If you are switching from another form of contraception, then DEPO-PROVERA should be given in a way that ensures you have continuous contraceptive cover. For example, patients switching from the oral contraceptive pill should have their first DEPO-PROVERA injection within 7 days after taking the last active pill.

If you miss a scheduled injection, your doctor will need to check that you are not pregnant before giving you another injection.

Endometriosis

The usual dosage is either 50 mg weekly or 100 mg every two weeks.

Treatment for endometriosis is usually for at least 6 months.

Endometrial and Renal Cancer

The initial dose range is 500 to 1000 mg per week.

If you respond to treatment and your condition is stable, a maintenance dose of 500 mg a week or less may be possible.

Your doctor will determine how much you will receive and how long you should continue to receive the injections.

Breast Cancer

The usual dosage for breast cancer is 500 mg to 1000 mg daily for 28 days.

If you respond to treatment, a dose of 500 mg twice weekly may be given.

Your doctor will determine how much you will receive and how long you should continue to receive the injections.

If you use too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have been given too much DEPO-PROVERA.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Overdose is unlikely as treatment will be given by your doctor or a health professional. Ask your doctor or pharmacist if you have any concerns.

While you are being treated with DEPO-PROVERA

Things you must do

If you become pregnant while using DEPO-PROVERA, tell your doctor.

If you have a sudden partial or complete loss of vision or sudden onset of double vision or migraine while you are using DEPO-PROVERA, tell your doctor immediately.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being treated with DEPO-PROVERA.

Tell any other doctors, dentists, and pharmacists who treat you that you are are being treated with DEPO-PROVERA, particularly if you are about to have any pathology tests (e.g., blood or urine tests).

DEPO-PROVERA may interfere with the results.

Do not use DEPO-PROVERA to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop using your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how DEPO-PROVERA affects you.

DEPO-PROVERA generally does not cause any problems with your ability to drive a car or operate machinery. However, DEPO-PROVERA may cause dizziness, drowsiness or fatigue in some people. Make sure you know how DEPO-PROVERA affects you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well during or after treatment with DEPO-PROVERA.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. However, you may need medical treatment if you get certain side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Most women using DEPO-PROVERA for contraception experience changes in their normal monthly period. This includes irregular or unpredictable bleeding or spotting, or rarely, heavy or continuous bleeding. If abnormal bleeding continues or is severe, see your doctor immediately.

With continued use of DEPO-PROVERA, it is usual for vaginal bleeding to decrease. Your periods may stop completely.

When you stop treatment with DEPO-PROVERA, your periods will return. However, this may take up to 18 months. Most women find that it takes about 10 months after their last injection to become pregnant. The length of time that you use DEPO-PROVERA does not affect the time it takes for you to become pregnant. If you do not wish to become pregnant after you stop treatment with DEPO-PROVERA, you or your partner

should use another form of contraception.

A reduction in the amount of calcium stored in your bones leading to brittle bones (osteoporosis) or fractures may occur. Talk to your doctor if you have any concerns over the risk of developing osteoporosis.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nervousness
- euphoria
- loss of concentration
- trouble sleeping
- drowsiness or sleepiness
- fatigue
- depression
- dizziness
- headache
- tremor or shaking
- hives, rash or itching
- acne
- excessive hair growth
- unusual hair loss or thinning
- sweating
- nausea
- vomiting
- diarrhoea
- constipation
- dry mouth
- breast tenderness, pain or secretions
- changes in vaginal secretions
- irregular vaginal bleeding or spotting
- lack of menstrual periods
- weight changes (increase or decrease)
- high fever
- abdominal pain, bloating or discomfort
- decreased libido or the inability to climax
- backache
- leg cramps
- joint pain
- pelvic pain
- pain and inflammation of the vagina
- swelling or puffiness
- change in facial shape (round appearance)
- fluid retention
- hot flushes
- change in appetite
- generally feeling unwell
- impotence (in men being treated for cancer).

Tell your doctor as soon as possible if you notice the following:

- confusion
- yellowing of the skin and eyes
- abnormal liver function test
- changes in body fat (e.g., an increased amount of fat in the upper back, neck, breast, and trunk, and loss of fat from the legs, arms, and face
- pain, tenderness, lump, indentation, thinning of the skin, inflammation or abscess formation at the injection site.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- sharp chest pain or coughing up blood
- weakness or numbness in your arms or legs
- fainting
- severe headaches or changes in speech or vision, loss of coordination, slurred speech, shortness of breath, chest pain, numbness heat or painful swelling in the arms or legsswollen or tender veins
- sudden, painless loss of vision in one eye as a result of blood clots in the retina at the back of the eye
- sudden onset of migraine
- severe abdominal pain
- increase in heart rate
- abnormal heart beat
- seizures
- vision problems.

These may be signs of a serious side effect. You may need urgent medical attention. Serious side effects are rare.

Some side effects (e.g, increase in blood pressure, increases in white blood cells and blood platelet count, osteoporosis) can only be found when your doctor does tests from time to time to check your progress.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After treatment with DEPO-PROVERA

Storage

Normally you should take your DEPO-PROVERA straight from the pharmacy to your doctor.

If, for any reason you take your DEPO-PROVERA home, always ensure that it is stored in a place where children cannot reach it.

It is important to store your DEPO-PROVERA in a safe place that is cool and dry (below 25°C).

Do not leave your DEPO-PROVERA in a car.

Do not store DEPO-PROVERA or any other medicine in the bathroom or near a sink.

Disposal

If the DEPO-PROVERA has passed its expiry date, return it to your pharmacist.

Product description

What it looks like

DEPO-PROVERA is a white cloudy liquid.

DEPO-PROVERA is available as a 1 mL disposable syringe.

Ingredients

Each syringe of DEPO-PROVERA contains medroxyprogesterone acetate as active ingredient.

It also contains:

- macrogol 3350
- polysorbate 80
- sodium chloride
- methyl hydroxybenzoate
- propyl hydroxybenzoate
- Water for Injections.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

DEPO-PROVERA is supplied in New Zealand by:

Pfizer New Zealand Limited

PO Box 3998

Auckland, New Zealand

Toll Free Number: 0800 736 363.

Date of preparation

This leaflet was prepared in November 2016.

® Registered Trademark.