

DEPO-PROVERA[®]

Medroxyprogesterone acetate

Aqueous suspension injection 150 mg/mL

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 taking Depo-Provera against the benefits it is expected to have for you.

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

Keep this leaflet with the medicine. 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:

1. 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.

2. 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.

3. 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.

Your doctor may have prescribed Depo-Provera for another purpose. Ask your doctor if you have any questions about why Depo-Provera has been prescribed for you.

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

Before you are given Depo-Provera

When you must not be given it

Do not use Depo-Provera 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
- Any lumps in your breasts that have not been diagnosed.
- any bleeding or discharge from your nipples
- Severe, uncontrolled, high blood pressure.

Do not take Depo-Provera if you have an allergy to medroxyprogesterone acetate or any of the ingredients listed at the end of this leaflet.

Do not use Depo-Provera if you are pregnant or intend to become pregnant.

Do not use Depo-Provera after the expiry date (EXP) printed on the pack.

Do not use Depo-Provera if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking/using Depo-Provera, talk to your doctor or pharmacist.

Before you are given it

You must tell your doctor if:

1. you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

2. you are pregnant or intend to become pregnant

3. you are breast feeding or plan to breast feed

4. you have or have had any medical conditions, especially the following:

- blood clots in your legs
- swollen and red veins
- stroke
- breast cancer or a family history of breast cancer
- any problems with your breasts
- unusual or irregular vaginal bleeding or spotting
- blood pressure problems
- epilepsy
- migraine
- asthma

- heart problems
- kidney problems
- liver problems
- diabetes
- depression
- a lack of normal menstrual periods
- bone disease or a family history of bone disease, such as brittle bones (osteoporosis)
- eating disorders (anorexia)

If you have not told your doctor or pharmacist about any of the above, tell him/her before 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. Talk to your doctor about how to avoid these diseases.

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.

The use of 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. The amount of calcium in your bones will start to increase again once you stop treatment with DEPO-PROVERA.

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may interfere with Depo-Provera. These include aminoglutethimide, a medicine used to treat breast cancer. This medicine may affect how well Depo-Provera works. You may need different amounts of your medicine or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist may have more information on medicines to be careful with or avoid while using Depo-Provera.

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 amount of Depo-Provera and the number of injections that you receive will depend on the reason that your doctor has prescribed it.

The dose for contraception and for endometriosis is a lot less than for cancer.

How much is given

1. Contraception

The recommended dose of Depo-Provera for effective contraception is 150 mg every three months. The contraceptive protection of Depo-Provera starts as soon as you have the first injection.

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

If you are using Depo-Provera as a contraceptive for the first time, your first injection should only 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 if 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 the time between your injections is greater than 13 weeks, your doctor will need to check that you are not pregnant before they give you another injection.

2. 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.

3. Endometrial and Renal Cancer

The initial dose range of Depo-Provera is 500 to 1000 mg.

There may be further treatment with an injection of 500 mg a week or less.

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

4. Breast Cancer

The usual dosage for breast cancer is 500 mg every day for 4 weeks. After the first 4 weeks, Depo-Provera is then given as a twice-weekly injection of 500 mg.

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

Overdose

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 using Depo-Provera

Things you must do

If you become pregnant while using Depo-Provera, tell your doctor. (The chance of falling pregnant while using Depo-Provera, as a contraceptive, is very low).

If you have a sudden partial or complete loss of vision or sudden onset of double vision or migraine while you are taking Depo-Provera, tell your doctor immediately.

Tell all doctors, dentists, and pharmacists who are treating you that you are using 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.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are using Depo-Provera.

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 you react to Depo-Provera before driving a car or operating machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using 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 using 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 using 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. Tell your doctor if this worries you.

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

- Nervousness
- Seizures
- Vision problems
- Confusion
- 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
- Yellowing of the skin or eyes
- Breast tenderness, pain or secretions
- Unusual changes in vaginal secretions
- Irregular vaginal bleeding or spotting
- Lack of menstrual periods
- Weight changes
- High fever
- Inflammation or abscess formation at the injection site
- Abdominal pain, bloating or discomfort
- Decreased libido or the inability to climax
- Backache
- Leg cramps
- Increase in heart rate
- Abnormal heart beat
- 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

Tell your doctor or pharmacist immediately 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 pain or swelling in your calf
- Severe abdominal pain

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

Some side effects (for example, increase in blood pressure, increases in white blood cells and blood platelet count) 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 using Depo-Provera

Storage

Normally you should take your Depo-Provera straight from the pharmacy to your doctor. 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.

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

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.

Inactive ingredients include macrogol 3350, polysorbate 80, sodium chloride, methyl hydroxybenzoate, propyl hydroxybenzoate and water for injections.

Depo-Provera does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Depo-Provera is supplied in New Zealand by:

Pfizer New Zealand Ltd
PO Box 3998
Auckland, New Zealand
Toll Free Number : 0800 736 363

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