

DEPO-RALOVERA®

Medroxyprogesterone acetate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DEPO-RALOVERA.

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-RALOVERA against the benefits they expect it will 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-RALOVERA is used for

The active ingredient of DEPO-RALOVERA is a chemical similar to the natural hormone progesterone. Your ovaries

produce progesterone during the second half of your monthly cycle.

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

DEPO-RALOVERA is used for the following reasons.

Contraception

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

DEPO-RALOVERA works by inhibiting the hormones that are needed for the release of eggs from your 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-RALOVERA helps to stop the growth of cells outside the uterus.

Cancer

DEPO-RALOVERA 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-RALOVERA is not a cure for cancer.

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

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

Before you are given DEPO-RALOVERA

When you must not be given it

DEPO-RALOVERA should not be used 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 breast that have not been diagnosed
- any bleeding or discharge from your nipples
- severe, uncontrolled, high blood pressure.

DEPO-RALOVERA should not be used if you are pregnant or intend to become pregnant.

DEPO-RALOVERA should not be used if you have an allergy to medroxyprogesterone acetate or any of the ingredients listed at the end of this leaflet.

DEPO-RALOVERA should not be used after the expiry date (EXP) 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 DEPO-RALOVERA, talk to your doctor or pharmacist.

Before you are given it

DEPO-RALOVERA does not protect against sexually transmitted infections (STIs) including HIV infection. Using DEPO-RALOVERA as directed will not expose you to STIs, as it is a sterile injection product.

Practising safe sex (ie. Using condoms) can lower the risk STI transmission, including HIV through sexual contact.

You must tell your doctor if you have allergies to:

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

You must tell your doctor if you are pregnant, suspect you may be pregnant or intend to become pregnant.

You must tell your doctor if you are breastfeeding or plan to breastfeed.

You must tell your doctor if you have or have had any medical conditions, especially the following:

- blood clots in your legs
- swollen 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
- abnormal 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 them before you are treated with DEPO-RALOVERA.

DEPO-RALOVERA 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-RALOVERA, 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-RALOVERA results 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-RALOVERA and if you continue using DEPO-RALOVERA for more than 2 years. The amount of calcium in your bones will start to increase again once you stop treatment with DEPO-RALOVERA. The time to recovery depends on duration of use. Some women may only partially recover the amount of calcium in their bone.

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 any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may interfere with DEPO-RALOVERA. These include aminoglutethimide, a medicine used to treat breast cancer. This medicine may affect how well DEPO-RALOVERA 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 being treated with DEPO-RALOVERA.

How DEPO-RALOVERA is given

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

The amount of DEPO-RALOVERA and the number of injections that you receive will depend on the reason for the treatment.

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

How much is given

Contraception

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

It is very 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-RALOVERA 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-RALOVERA as a form of contraception after the birth of your baby and if you are not breastfeeding, the first injection should be given within 5 days after the baby was born.

If you are breastfeeding, the first injection should be given 6 weeks after the baby was born and after your doctor has checked that you are not pregnant.

If you are switching from another form of contraception, then DEPO-RALOVERA 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-RALOVERA injection within 7 days after taking the last active pill.

If the time between your injections is greater than 14 weeks, your doctor will need to check that you are not pregnant before they give 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.

Breast Cancer

The usual dosage for breast cancer is 500 mg every day for 4 weeks. After the first 4 weeks, DEPO-RALOVERA is given as a weekly injection of 500 mg or 1000 mg.

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

Other types of cancer

The initial dose range of DEPO-RALOVERA is 600 mg to 1200 mg every week. This is followed by an injection of 450 mg to 600 mg every 1 to 4 weeks.

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

If you are given too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) or go to Accident and Emergency at your nearest hospital if you think you or anyone else may have been treated with too much DEPO-RALOVERA.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using DEPO-RALOVERA

Things you must do

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

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

Tell all doctors, dentists, and pharmacists who are treating you that you have been treated with DEPO-RALOVERA, particularly if you are about to have any pathology tests (e.g. blood or urine tests). DEPO-RALOVERA may interfere with the results.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you have been treated with DEPO-RALOVERA.

Things to be careful of

Be careful driving or operating machinery until you know how DEPO-RALOVERA affects you. DEPO-RALOVERA generally does not cause any problems with your ability to drive a car or operate machinery. However, DEPO-RALOVERA may cause dizziness, drowsiness or fatigue in some people. Make sure you know how you react to DEPO-RALOVERA before driving a car or operating machinery.

Side effects

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

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 some side effects.

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

Most women using DEPO-RALOVERA 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-RALOVERA, it is usual for vaginal bleeding to decrease. Your periods may stop completely.

When you stop treatment with DEPO-RALOVERA, your periods will return. However, this may take up to 18 months. Most women find that it takes 12 to 18 months after their last injection to become pregnant. The length of time that you use DEPO-RALOVERA 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-RALOVERA, 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
- 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
- breast tenderness or secretions
- changes in vaginal secretions
- irregular vaginal bleeding or spotting
- lack of menstrual periods
- weight increases or decrease
- high fever

- abscess formation at the injection site
- abdominal pain, bloating or discomfort
- decreased libido or the inability to climax
- backache
- leg cramps
- muscle spasms
- joint pain
- pain and inflammation of the vagina
- swelling or puffiness
- fluid retention
- hot flushes
- vision problems
- impotence (in cancer treated patients).

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
- sudden onset of migraine
- severe abdominal pain.
- changes in metabolism resulting in the loss of body fat in certain areas of your body such as your face.
- hand tremors, sweating, cramps in calves at night.
- yellowing of the skin and/or eyes.

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

Other side effects not listed above may occur in some patients. These include side effects that can only be detected with a blood test. 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-RALOVERA

Storage

Keep DEPO-RALOVERA in a cool dry place where the temperature stays below 30°C. Normally you should take

DEPO-RALOVERA straight from the pharmacy to your doctor. Do not leave it in a car.

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

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

Disposal

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

Product description

What it looks like

DEPO-RALOVERA is a white cloudy liquid.

Ingredients

Each vial of DEPO-RALOVERA contains medroxyprogesterone acetate as an active ingredient.

In addition, each vial contains macrogol 3350, polysorbate 80, sodium chloride, methyl hydroxybenzoate, propyl hydroxybenzoate and Water for Injections.

DEPO-RALOVERA does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Identification

DEPO-RALOVERA vials can be identified by the Australian Register Number on the carton:

150 mg/1mL: AUST R 44464

Supplier

DEPO-RALOVERA is supplied in Australia by:

Pfizer Australia Pty Ltd

ABN 50 008 422 348

38-42 Wharf Road

West Ryde NSW 2114

Australia.

Toll free number: 1800 675 229.

This leaflet was revised January 2018

© Pfizer Australia Pty Ltd 2015.

®Registered Trademark.