

DEPO-RALOVERA®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using DEPO-RALOVERA?

DEPO-RALOVERA contains the active ingredient medroxyprogesterone acetate. DEPO-RALOVERA is used as a form of contraception, to treat endometriosis and certain types of cancer including cancer of the breast, kidney and endometrium (lining of the uterus).

For more information, see Section [1. Why am I using DEPO-RALOVERA?](#) in the full CMI.

2. What should I know before I use DEPO-RALOVERA?

Do not use if you have ever had an allergic reaction to medroxyprogesterone acetate or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant, plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use DEPO-RALOVERA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DEPO-RALOVERA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is DEPO-RALOVERA 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.

More instructions can be found in Section [4. How is DEPO-RALOVERA given?](#) in the full CMI.

5. What should I know while using DEPO-RALOVERA?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using DEPO-RALOVERA.• Tell your doctor immediately if you have sudden partial or complete loss of vision or sudden onset of double vision or migraine while you are using DEPO-RALOVERA.• Tell your doctor if you are pregnant or have become pregnant while using DEPO-RALOVERA.• Tell your doctor if you are about to have any pathology tests (e.g. blood or urine tests).
Driving or using machines	<ul style="list-style-type: none">• Do not drive or operate machinery until you know how DEPO-RALOVERA affects you. DEPO-RALOVERA may cause dizziness, sleepiness or affect vision in some people.
Looking after your medicine	<ul style="list-style-type: none">• Keep DEPO-RALOVERA in a cool dry place where the temperature stays below 30°C. Do not keep it in the refrigerator or freezer. Normally you should take DEPO-RALOVERA straight from the pharmacy to your doctor. Do not leave it in a car.• Keep out of reach of children.• Follow the instructions in the carton on how to take care of your medicine properly.

For more information, see Section [5. What should I know while using DEPO-RALOVERA?](#) in the full CMI.

6. Are there any side effects?

There are a number of side effects associated with this medicine. See the full CMI for more details. The most common and serious side effects are: nausea, dizziness, headache, fatigue or sleepiness, trouble sleeping, hot flushes, changes in mood or mental state, changes to menstrual period or vaginal secretions, skin problems, excessive hair growth or loss, breast tenderness or secretions, weight changes, bloating or swelling, decreased libido, vision problems, allergic reactions, pressure or tightness in the chest, pain, discomfort or weakness in the back, legs, joints, pelvis, calves or abdomen, fainting, sudden migraine onset, hand tremors, seizures, paralysis or yellowing of the skin and/or eyes.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

DEPO-RALOVERA®

Active ingredient(s): *medroxyprogesterone acetate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using DEPO-RALOVERA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using DEPO-RALOVERA.**

Where to find information in this leaflet:

- [1. Why am I using DEPO-RALOVERA?](#)
- [2. What should I know before I use DEPO-RALOVERA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is DEPO-RALOVERA given?](#)
- [5. What should I know while using DEPO-RALOVERA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using DEPO-RALOVERA?

DEPO-RALOVERA contains the active ingredient medroxyprogesterone acetate. DEPO-RALOVERA is a progestogen, similar to the natural hormone progesterone. Your ovaries produce progesterone during the second half of your monthly cycle.

DEPO-RALOVERA is used as a form of contraception, to treat endometriosis and also certain types of cancer including cancer of the breast, kidney and endometrium (lining of the uterus).

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.

2. What should I know before I use DEPO-RALOVERA?

Warnings

Do not use DEPO-RALOVERA if:

- you are allergic to medroxyprogesterone acetate, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

- you have or have had any of the following medical conditions:
 - swelling and redness along a vein (usually extremely tender when touched)
 - a stroke or blood clots
 - liver problems
 - unusual or irregular vaginal bleeding that has not been diagnosed
 - blood in your urine that has not been diagnosed
 - any lumps or issues with your breast that have not been diagnosed, including any bleeding or discharge from your nipples.
 - a missed miscarriage
 - severe, uncontrolled, high blood pressure
 - breast cancer, whether known or suspected (except when used for cancer treatment).
- you are pregnant or suspect you may be pregnant.
- it has passed the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- have allergies to any medicines, foods, preservatives or dyes.
- Have or have had any other medical conditions, such as:
 - blood clots in your legs, lungs or anywhere else in your body
 - swollen red veins
 - stroke
 - brain and/or spinal cord tumour or abnormal growths
 - liver problems
 - unusual or irregular vaginal bleeding or spotting
 - abnormal menstrual periods
 - breast cancer or a family history of breast cancer
 - any problems with your breasts
 - blood pressure problems
 - epilepsy
 - migraine
 - asthma
 - heart problems
 - kidney problems
 - diabetes

- depression
- bone disease, or a family history of bone disease, such as brittle bones (osteoporosis)
- vision problems
- fluid retention issues
- eating disorders (anorexia).
- take any medicines for any other condition.

Some medicines 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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Physical examinations

Before prescribing DEPO-RALOVERA for you, your doctor may conduct a physical examination which may include breast and pelvic examinations and/or a PAP smear.

Sexually transmitted infections (STIs)

- 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.
- 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 of STI transmission, including HIV, through sexual contact.

Breast cancer

- 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.

Bone mineral density (BMD) changes

- 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.

3. What if I am taking other medicines?

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

Medicines that may reduce the effect of DEPO-RALOVERA include:

- aminoglutethine, a medicine used for the treatment of breast cancer.

Your doctor or pharmacist may have more information on medicines to be careful with or avoid while being treated with DEPO-RALOVERA.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DEPO-RALOVERA.

4. How is DEPO-RALOVERA 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 much lower 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 forget to use DEPO-RALOVERA

DEPO-RALOVERA should be given as determined by your doctor.

It is important to keep your appointments with the doctor who will determine your dosing schedule.

If too much DEPO-RALOVERA is given

If you think that you or anyone else may have been treated with too much DEPO-RALOVERA, you or the person may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using DEPO-RALOVERA?

Things you should do

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.

Call your doctor straight away if you:

- become pregnant while using DEPO-RALOVERA. 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 using DEPO-RALOVERA, tell your doctor immediately.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how DEPO-RALOVERA affects you.

DEPO-RALOVERA may cause dizziness, sleepiness or affect vision in some people. Make sure you know how you react to DEPO-RALOVERA before driving a car or operating machinery.

Drinking alcohol

Tell your doctor if you drink alcohol.

There is no information on how DEPO-RALOVERA and alcohol may interact.

Looking after your medicine

- Keep DEPO-RALOVERA in a cool dry place where the temperature stays below 30°C. Do not keep it in the refrigerator or freezer. 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Do not use this medicine after the expiry date.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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

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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

Side effects	What to do
<p>Changes to your mood or energy levels:</p> <ul style="list-style-type: none"> nervousness, confusion increased heart rate euphoria loss of concentration depression fatigue, drowsiness or sleepiness trouble sleeping <p>General feeling of being unwell:</p> <ul style="list-style-type: none"> nausea, vomiting, diarrhoea or constipation dizziness, headache sweating hot flushes high fever <p>Changes to your hair, skin or eyes:</p> <ul style="list-style-type: none"> hives, rash or itching acne, darkening patches of skin on the cheeks excessive hair growth or unusual hair loss or thinning vision problems <p>Changes to your digestive or urinary system and/or metabolism:</p> <ul style="list-style-type: none"> dry mouth, increased thirst weight increases or decreases changes in appetite abdominal pain, bloating or discomfort frequently urinating 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Side effects	What to do
<p>Changes to your reproductive system:</p> <ul style="list-style-type: none"> breast tenderness or secretions pain during sex changes in vaginal secretions irregular vaginal bleeding or spotting lack of menstrual periods decreased libido or the inability to climax impotence (in men being treated for cancer) pain and inflammation of the vagina <p>Pain or swelling in your body:</p> <ul style="list-style-type: none"> abscess formation at the injection site backache, leg cramps, muscle spasms joint pain swelling or puffiness, fluid retention 	

Serious side effects

Serious side effects	What to do
<p>Signs of an allergic reaction, such as:</p> <ul style="list-style-type: none"> 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 <p>Pain or discomfort in your body:</p> <ul style="list-style-type: none"> pressure or tightness in the chest, back or jaw pain, difficulty breathing, or coughing up blood weakness or numbness in your arms or legs severe pain or swelling in your calf sudden onset of migraine severe abdominal pain hand tremors, sweating, cramps in calves at night <p>Changes to your body, face or eyes:</p> <ul style="list-style-type: none"> changes in metabolism resulting in the loss of body fat in certain areas of your body such as your face yellowing of the skin and/or eyes <p>Other:</p> <ul style="list-style-type: none"> seizures, paralysis fainting memory loss 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> hearing loss 	

Other side effects not listed here may occur in some people. These include side effects that can only be detected with a blood test.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What DEPO-RALOVERA contains

Active ingredient (main ingredient)	medroxyprogesterone acetate
Other ingredients (inactive ingredients)	macrogol 3350 polysorbate 80 sodium chloride methyl hydroxybenzoate propyl hydroxybenzoate water for Injections

Do not use this medicine if you are allergic to any of these ingredients.

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

What DEPO-RALOVERA looks like

DEPO-RALOVERA is a white cloudy liquid. DEPO-RALOVERA contains 150 mg of medroxyprogesterone acetate in 1 mL solution. DEPO-RALOVERA is supplied as a vial (AUST R 44464).

Who distributes DEPO-RALOVERA

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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