

Jadelle®

levonorgestrel-releasing implant 75 mg x 2

What is in this leaflet

Please read this leaflet carefully before you start using Jadelle.

This leaflet answers some common questions about Jadelle. 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 using Jadelle against the benefits they expect it will 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 Jadelle is used for

Jadelle is a contraceptive implant, used to prevent pregnancy. Contraceptive implants such as Jadelle are for long term (up to five years) use.

The implants contain a synthetic hormone, levonorgestrel, which is also one of the active ingredients used in many oral contraceptives. Immediately after the insertion of Jadelle implants, low doses of the hormone start to be released continuously into your body. Jadelle prevents pregnancy through a combination of mechanisms. The most important of these are inhibition of the egg release by stopping it maturing and changing the cervical mucus consistency, making it more difficult for sperm to reach the egg. Other mechanisms may also be involved. When Jadelle implants are removed, your fertility will resume.

Jadelle is inserted just beneath the skin on the inside of your upper arm and is performed by your doctor.

Although the implant may be removed at any time, it must be removed no later than five years after insertion.

If you weigh over 60 kg, your doctor may recommend that you have the implant removed or have a new implant inserted after the 4th year.

Your doctor may have prescribed Jadelle for another reason.

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

Before you use Jadelle

When you must not use it

Do not use Jadelle if:

- you have or have had a blood clot (in your legs, lungs or other parts of your body)
- you have or have had a liver tumour or liver disease as long as the liver function values have not returned to normal
- you have or are suspected of having cancer relating to sex hormones
- you have abnormal vaginal bleeding.

Do not use Jadelle if have an allergy to:

- any medicine containing levonorgestrel
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not use this medicine if you are pregnant or you think you may be pregnant. It may affect your developing baby if you use Jadelle during pregnancy.

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 it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using Jadelle, talk to your doctor.

Before you start to use it

Before inserting Jadelle implants your doctor will ask about your medical history, perform a physical examination and make sure that you are not pregnant. After some time has elapsed from the insertion, your doctor may want to check the implant site. As with other hormonal contraceptives, you will need regular check-ups while you are using Jadelle implants. Your doctor will tell you how often.

You can decide to have your Jadelle implants removed at any time. Removal may be more difficult than the insertion. It may take longer and involve more pain. In a small proportion of users (approximately 1.5%) the removal of Jadelle was considered by the women concerned to have adversely affected them. This could include being difficult to remove, requiring a long incision or more than one visit to have the rods removed. Jadelle may also leave scars, a risk that does not exist with some other contraceptive methods.

Following insertion, there have been some reports of slight displacement of Jadelle and other levonorgestrel implants, which have been associated with some reports of pain or discomfort. If displacement occurs, this may involve additional incisions or visits for the removal of Jadelle.

Jadelle implants are different from other contraceptive methods. Some doctors have more experience than others with inserting and removing Jadelle. Discuss with your doctor or nurse to find out whether your doctor is familiar with the insertion and removal of Jadelle implants.

Once Jadelle is inserted, it may change your menstrual bleeding patterns. You may experience irregular bleeding, bleeding between periods, longer periods, spotting or no

bleeding at all. For most women these irregularities will diminish gradually with continuing use.

In rare cases benign liver tumours and even more rarely, malignant liver tumours have been reported in users of hormonal contraceptives such as Jadelle. These tumours may lead to internal bleeding. Contact your doctor immediately if you have severe pain in your abdomen.

Increased pressure around the brain (idiopathic intracranial hypertension) has been reported rarely in users of levonorgestrel implants such as Jadelle. You should contact your doctor if you experience frequent, severe or persistent headaches or have problems with your vision.

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

Not all women can use Jadelle implants. Your doctor may advise you to use a different type of hormonal contraception or an entirely different (non-hormonal) method of birth control.

Tell your doctor if:

- you have had an ectopic pregnancy (where the foetus is carried outside of your womb)
- you or someone in your family has a history of thrombosis or a blood clotting disorder, stroke, heart attack or coronary artery disease
- you have risk factors for blood clots
- you have or have had migraines or frequent headaches
- you are breast-feeding
- you have or have had lumps in your breast, mastopathy (breast disease) or an abnormal mammogram (breast X-ray picture) or someone in your family has had breast cancer
- you have diabetes
- you have liver disease
- you have depression
- you have a condition which may worsen with fluid retention
- you wear contact lenses
- you have abdominal pain
- you have not had your menstrual periods
- you have or have had inflammation of your veins (superficial phlebitis)
- you have the following inflammatory diseases: scleroderma (thickening and hardening of the skin), lupus erythematosus disseminate (a disease affecting the skin all over the body) or rheumatoid arthritis (disease affecting the joints)
- you have a condition that occurred with previous use of sex hormones or during pregnancy (e.g. itching, gall stones, haemolytic uraemic syndrome – a disorder of blood clotting causing failure of the kidneys, hearing loss or a skin disease called herpes gestationis).

If you have not told your doctor about any of the above, tell them before you start using Jadelle.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are using Jadelle.

Some medicines may interfere with Jadelle. These include:

- medicines used to treat epilepsy, such as phenytoin, primidone, barbiturates (e.g. phenobarbitone), carbamazepine, oxcarbazepine, topiramate, felbamate, lamotrigine
- medicines used to treat tuberculosis, such as rifampicin
- medicines used to treat bacterial infections, such as clarithromycin, erythromycin
- medicines used to treat fungal infections, such as griseofulvin, itraconazole, voriconazole, fluconazole
- medicines used to HIV or hepatitis C virus (HCV) such as efavirenz, nelfinavir, ritonavir, darunavir, (fos)amprenavir, lopinavir, tipranavir, nevirapine, indinavir, atazanavir, etravirene
- medicines used to treat pulmonary hypertension (high blood pressure in the lung vessels), such as bosentan
- medicines containing St John's Wort
- medicines used to treat high blood pressure, chest pain or irregular heartbeats, such as verapamil, diltiazem
- medicines used after organ transplantation such as cyclosporine
- grapefruit juice

These medicines may affect how well Jadelle works. You may need to use additional non hormonal (barrier) methods of contraception (such as condoms or diaphragm) while you are taking any of these medicines and for four weeks after stopping them. Your doctor will be able to advise you about how long you will need to use additional contraceptive methods.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using Jadelle.

How to use Jadelle

Jadelle is effective for 5 years after administration and can be removed at any time.

When to start using Jadelle

If you have not used a hormonal contraceptive in the past month, Jadelle should be inserted within 7 days from the onset of your menstrual period. If the implants are inserted at any other time, pregnancy must be excluded before insertion, and make sure you also use additional non hormonal (barrier) methods (e.g. condoms) for at least 7 days after insertion.

Your doctor will advise you when to use Jadelle:

- after having a baby
- if you are breast-feeding
- if you have had a miscarriage or an abortion.

Changing from a combined hormonal contraceptive (combined oral contraceptive, vaginal ring or patch)

If you are switching from a combined oral contraceptive, Jadelle should be inserted on the day after taking the last active tablet or at the latest, on the day after the tablet free interval or placebo tablet phase. However, in this instance you will need to make sure you also use additional non hormonal (barrier) methods (e.g. condoms or a diaphragm) during the last tablet free interval or placebo tablet phase before switching to Jadelle.

If you are switching from a vaginal ring or patch, Jadelle should be inserted on the day of removal of the last ring or patch of the cycle or at the latest, when the next ring or patch is due.

Changing from a progestogen only method (minipill, injection, implant) or from a progestogen-releasing intrauterine system (IUS)

Jadelle should be inserted the day when you stop taking the minipill, when your next injection is due, or on the day that your implant or IUS is removed.

Insertion of Jadelle implants

Jadelle implants must be inserted and removed by a health professional who is familiar with the procedure. The two thin Jadelle implants will be inserted just beneath the skin on the inside of your upper arm with a special inserter called a trocar. This will involve a minor surgical procedure. If you are right-handed, usually your left arm is used, and if you are left handed, your right arm.

A local anaesthetic will be used as a small incision has to be made to insert the rods. The two rods are placed underneath the skin, one at a time. Since a local anaesthetic is used, you should not feel any pain. There may be some discolouration, bruising or swelling at the implant site for a few days after the insertion but these should not interfere with your normal activities.

Occasionally, an infection may occur or there may be transient pain or itching. The following skin reactions have been reported in connection with the insertion of other similar levonorgestrel implants: scarring, blistering, sloughing, ulceration, tingling and numbness.

After the procedure, the insertion site will be closed with a skin closure and bandaged. Keep the wound dry and bandaged for three days. Do not bump the insertion site or lift anything heavy with that arm during this time.

When and how JADELLE implants are removed

Jadelle implants must be removed at the end of five years by a trained doctor. If you want to continue using Jadelle implants, a new set can be inserted when the rods are removed. If you weigh over 60 kg, your doctor may recommend the removal and change of implants after the fourth year of use. Do not put off the removal after the five years have elapsed, since the implants will start to lose their effectiveness after that period. If you cannot see a doctor in time to have the implants removed at the end of the fifth year, you must use additional non hormonal (barrier) methods (e.g. condoms) and have the implants removed as soon as possible.

If you do not want to have another set of Jadelle implants inserted and do not wish to become pregnant, **you must start using another method of contraception immediately after the removal.** The contraceptive effect of Jadelle stops very quickly after they have been removed.

If you want to stop using Jadelle before five years, the implants can be removed at any time. If you do not wish to become pregnant, **you must start using another method of contraception immediately.**

Removal of Jadelle implants

The Jadelle implants must be removed by a trained doctor. Do not try to remove them yourself. The implant site will be anaesthetised and a small cut will be made in the skin. After removal, keep the wound clean, dry and bandaged for 3 to 5 days or until the skin has healed. The removal of Jadelle implants will usually take more time than the insertion. Bruising may occur at the site following removal. If the rods are found to be too deep, they may be more difficult to remove. If both rods cannot be removed at the first attempt, you will need to see the doctor again for another attempt. You should use another method of contraception until both rods have been removed.

In cases where removal of the rods has been difficult, there have been reports of pain, numbness, tingling and scarring in the upper arm.

While you are using Jadelle

Things you must do

If you are about to be started on any new medicine tell your doctor and pharmacist that you are using Jadelle.

See your doctor immediately if you notice possible signs of thrombosis. These include:

- an unusual cough
- severe pain or heaviness in the chest
- breathlessness
- any unusual, severe, or prolonged headache or migraine attack
- partial or complete loss of vision, or double vision
- slurring or speech disability
- sudden changes to your hearing, sense of smell, or taste
- dizziness or fainting
- weakness or numbness in any part of your body
- severe pain in your abdomen
- severe pain, swelling or discolouration in either of your legs.

If your blood pressure increases consistently during the use of Jadelle implants, or if your blood pressure increases significantly and cannot be controlled adequately with blood pressure medication, your doctor will remove the Jadelle implants.

If you are going to have surgery, tell the surgeon or anaesthetist beforehand that you are using this medicine. The risk of having deep venous thrombosis is temporarily increased as a result of an operation or immobilisation (for example, when you have your leg or legs in plaster or splints).

If you are about to have any blood tests, tell your doctor that you are using this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests (such as blood tests, monitoring your blood pressure and checking the insertion site) from time to time to make sure the medicine is working and to prevent unwanted side effects.

If you become pregnant while using this medicine, tell your doctor immediately.

Jadelle will not protect you from HIV-AIDS or any other Sexually Transmitted Infections (STIs), such as chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B, human papilloma virus and syphilis. **To protect yourself from STIs, you will need to use additional barrier contraceptives (e.g. condoms).**

In case of Overdose

If you take too much (overdose)

There is no experience of overdose with Jadelle.

Side Effects

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

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

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

The following list includes the more common side effects of your medicine. These are usually mild and lessen with time.

If you notice any of the following side effects and they worry you, tell your doctor or pharmacist:

- headache, migraine
- dizziness
- mood changes, depression, nervousness
- changes in libido
- abnormal heartbeat
- varicose veins
- abdominal discomfort, nausea
- acne
- loss of hair from the head or body, excessive hair growth
- rash, itching
- skin discolouration
- urinary tract symptoms such as a burning or frequent need to urinate
- changes in menstrual bleeding including irregular, prolonged, spotting, heavy, bleeding or spotting between periods or absence of bleeding
- itching, burning or abnormal vaginal discharge
- lumps in the breast, breast discharge, breast pain
- pelvic pain, back pain or pain in general
- itching at the injection site
- tiredness
- changes in weight

If you experience any of the following, tell your doctor immediately, or go to the Emergency Department at your nearest hospital:

- chest pain
- breathlessness and/or difficulty breathing
- painful or swollen leg(s)
- weakness, numbness or bad 'pins and needles' of an arm or leg
- severe, sudden stomach pains
- a bad fainting attack, or you collapse
- unusual headaches or migraines that are worse than usual and/or visual disturbances
- sudden problems with your speech or eyesight, yellowing of the skin and/or eyes (jaundice)
- lower abdominal pain
- nerve damage associated with removal of the implant
- dark patches on the skin over the implant site

You may need urgent medical attention or hospitalisation.

Jadelle implants may be expelled before the insertion area has healed, if this occurs please see your doctor immediately.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other unusual symptoms.

Storage

Store below 30°C.

Store all medicines properly and keep them out of reach of children.

Product description

What it looks like

The implants consists of two flexible, white to off-white rods 43 mm in length and 2.5 mm in diameter each containing 75 mg levonorgestrel. The sterile implants are packed in blisters.

Ingredients

Active ingredient:

- levonorgestrel 150 mg (2 x 75 mg implants)

Inactive ingredients:

- silicone elastomers, colloidal anhydrous silica

Sponsor Details

Made in Finland for:

Bayer New Zealand Limited
3 Argus Place, Hillcrest
North Shore AUCKLAND 0627

Free phone 0800 233 988

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This leaflet was prepared on 7 April 2015.

See MEDSAFE website (www.medsafe.govt.nz) for latest New Zealand Consumer Medicine Information.

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