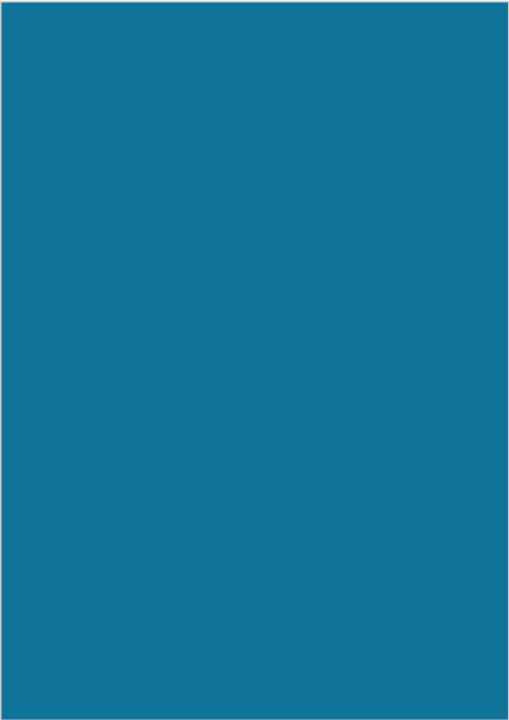




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Thank you for considering JADELLE®, a contraceptive implant used to prevent pregnancy.¹ Contraceptive implants such as JADELLE are among the most effective reversible contraceptive methods known.² When used correctly the chance of becoming pregnant is very low.¹

Your doctor may have already discussed JADELLE with you.

This leaflet contains important information about JADELLE and if you have any further questions after reading please speak to your doctor. Additional information can also be found in the JADELLE Consumer Medicine Information found at www.medsafe.govt.nz/consumers/cmi/j/jadelle.pdf

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What is JADELLE?

JADELLE is an effective, reversible contraceptive that prevents pregnancy for up to five years. Two thin, flexible rods containing a hormone are inserted just under the skin of your upper arm.¹

How does JADELLE work?

JADELLE implants continuously release a low dose of a synthetic hormone, levonorgestrel.

JADELLE prevents pregnancy in a number of ways. The most important of these are the inhibition of ovulation (prevents the release of an egg) and the thickening of the cervical mucus, making it more difficult for sperm to reach the egg. JADELLE contains no oestrogen.¹

How effective is JADELLE?

Although no contraception is 100% effective JADELLE is considered one of the most effective forms of contraception available. JADELLE is as effective as sterilisation while having the advantage of being completely reversible.² This means that if you want to get pregnant you can have JADELLE removed and you will return to your usual fertility right away.¹

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How long is JADELLE effective?

JADELLE will provide contraception for up to five years. Before the end of the fifth year, when the implants should be removed, a new set may be inserted for continued protection against pregnancy.¹ If you weigh over 60 kg, your doctor may recommend that you have a new implant inserted after the 4th year.⁴

Who can use JADELLE?

JADELLE may be used by most healthy women who do not wish to get pregnant.

It is a good method for women who need a very effective, long acting contraception, without needing to remember to take a pill every day, or prefer a contraceptive method without oestrogen.¹ JADELLE is fully funded.³ A prescription charge and doctors' fee for insertion may apply.



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Who should not use JADELLE?

Your doctor will consult with you to make sure that there are no medical reasons why you should not use JADELLE.

JADELLE should not be used if you have a blood clot, are sensitive to any ingredients in JADELLE or have abnormal bleeding from your vagina, have liver disease or abnormal liver function, have or have had a liver tumour, known or suspected breast cancer or other hormone dependent cancer, or if you are pregnant. If you become pregnant while using JADELLE it must be removed immediately by your doctor.¹

Are you taking any medication?

Certain medicines may interfere with the hormone delivered by JADELLE, making it less effective. 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. Please refer to the Consumer Medicine Information (CMI) for further information.

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When should JADELLE be inserted?

To make sure that you are not pregnant, the implants should be inserted within 7 days of the first day of your period, or immediately or within 7 days after abortion. If they are inserted at any other time your doctor will need to make sure you are not pregnant before insertion and you will need to use an additional non-hormonal (barrier) method (e.g. condoms) for the following 7 days.¹

How is JADELLE inserted?

JADELLE is inserted just under the skin in the inner part of your upper arm (your left arm if you're right-handed and right arm if you're left handed). This will involve a minor surgical procedure. The area will be cleaned and anaesthetic injected making the area numb. A small cut is made in the skin and the implants are inserted under the skin in the shape of a V. The small cut is closed with sterile tape and a dressing will be placed on your arm.¹

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.⁴



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The first days with JADELLE

After the anaesthetic wears off, you will probably experience some tenderness, swelling or bruising at the insertion site for the first few days, this should not interfere with your normal activities.⁴ Keep the insertion area dry for 3 days to prevent infection. The protective gauze and bandage may be removed after 3 days. The sterile skin closure can be removed as soon as the incision wound has healed, normally after 3-5 days.¹

You can resume your normal daily activities immediately following the insertion of JADELLE. However, you should not lift any heavy objects and you should try to avoid bumping the insertion site for a few days. After the incision has healed, you do not have to worry about bumping the area or putting pressure on it. The implants are flexible, generally they will stay where they are placed and not move around. Insertion or removal of the implants may leave a small scar on the arm.^{1,4}

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.⁴

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How will JADELLE affect my periods?

JADELLE is likely to alter your bleeding pattern. For most women these changes gradually lessen with continuing JADELLE use. The type of bleeding pattern you will experience with JADELLE cannot be predicted. Changes to your periods vary from woman to woman and may include bleeding for longer than usual during the first few months of use, bleeding between periods, no bleeding at all for several months, or a combination of these patterns.

If you have regular periods while using JADELLE and they suddenly stop for six weeks or more, you should confirm that you are not pregnant. If you are pregnant, JADELLE implants must be removed immediately by your doctor.¹

Will the implants move around?

Generally they will remain under the skin where they are placed. 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.⁴



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Side effects

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.

If you do not feel well or you are worried about possible side effects with JADELLE please tell your doctor, nurse or pharmacist immediately. The following list includes the more common side effects of JADELLE, they are usually mild and lessen with time. Do not be alarmed, you may not experience any of them.

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 or changes in weight.



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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.⁴

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

Can I use JADELLE when breastfeeding?

The hormone in JADELLE does not affect the quality or quantity of breast milk.¹

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Sexually transmitted infections and HIV

JADELLE is a contraceptive. It is not intended to protect against sexually transmitted infections (STIs) including HIV. To protect yourself from STIs you will need to use additional barrier contraceptives (i.e. condoms).¹

When to contact your doctor

You should contact your doctor or clinic right away if you have: heavy vaginal bleeding, arm pain, pus or bleeding at the insertion site, indicating infection, expulsion of an implant, episodes of migraine, repeated severe headaches or blurred vision, yellowing of your skin, depression or a delayed period after a long time of having regular cycles. Failure to have periods after regular periods may be a sign of pregnancy.^{1,4}

[no notes on this page]

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.



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Removal of JADELLE



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.

If you wish to continue using JADELLE, a new set of implants can be inserted at the same time as the old set is removed.¹

How soon after removal can I get pregnant?

JADELLE will not alter your future fertility. Once the implants are removed, the contraceptive effect wears off quickly and you may become pregnant.¹

[no notes on this page]

References: 1. Jadelle Data Sheet, 21 September 2020. 2. Trussell, J. Contraceptive failure in the United States. *Contraception*. 2011; 83: 397-404. 3. Pharmaceutical Schedule 2017. Accessed from www.pharmac.govt.nz on 29 October 2020. 4. JADELLE Consumer Medicine Information, September 2020.

JADELLE® (levonorgestrel), JADELLE® is a long-acting (up to 5 years) progestogen-only contraceptive implant. It consists of two flexible white rods 43 mm in length and 2.5 mm in diameter each containing 75 mg levonorgestrel. JADELLE is a **Prescription Medicine** used for contraception. JADELLE must not be used if you are pregnant or if you suspect you might be pregnant; if you have an active blood clotting disorder; if you have or have had a liver tumour or abnormal liver function; abnormal vaginal bleeding; sex-hormone-dependent cancers; or if you are sensitive to any of the ingredients of JADELLE. Careful consideration of the risks and benefits of JADELLE is required where there is a history of blood clots, heart attacks, stroke, diabetes with blood vessel damage or severe migraine. Use strictly as directed and inform your doctor immediately if any of the following occur: development or worsening of migraine; jaundice; depression; persistent headache; visual disturbances or changes to contact lens tolerance in contact lens wearers; severe abdominal pain together with no periods (an indication of a possible ectopic pregnancy); a nod is expelled; you have pus or bleeding at the injection site; you have a lump in your breast or a blood clot (possible warning signs are severe pain in the chest or breathlessness or severe pain or swelling in one of your legs); you develop breast cancer or a liver tumour; significant increase in blood pressure. Women with diabetes, a history of depression or conditions that might be worsened by fluid retention should be carefully monitored by their doctor. Side effects with JADELLE that may occur include headache, nervousness, dizziness, nausea, changes to your periods such as spotting or prolonged periods, inflammation of the cervix or vagina, vaginal discharge, genital itchiness, general pain or pain in the chest, back, lower abdomen or breasts, weight gain or loss, acne, bleeding or itching at the injection site, mood changes, depression, changes in libido, migraine, palpitations, high blood pressure, varicose veins, shortness of breath, abdominal discomfort, rise in total serum bilirubin, skin reactions such as rash, skin discolouration, itching, loss of hair from head or body, excessive hair growth, urinary tract symptoms, ovarian cysts, non-cancerous breast lumps, breast discharge, tenderness. If symptoms persist or you have side effects, see your doctor, pharmacist or health professional. Your doctor can give details of other less common side effects. Read the package insert carefully. In all situations where the reliability of JADELLE is reduced (such as a missing rod) additional contraceptive precautions are required.

JADELLE is a fully funded medicine. Normal Doctor's visit and insertion/removal fees may apply. This medicine has risks and benefits. Ask your doctor if JADELLE is right for you. Additional information is available from <https://www.medsafe.govt.nz/Consumers/cm/i/jadelle.pdf> or Bayer New Zealand Limited, PO Box 2825, Shortland Street, Auckland 1140, telephone 0900 223 988. ® Registered trademark of the Bayer Group, Germany. Approval No. PP-JAD-NZ-0008-1. TAPS NA 12522, November 2020, BY10001

1. This medicine has risks and benefits

Mandatory Amend to 'Jadelle has risks and benefits' to align with wording prescribed in Code Of Practice [Emily Macnaughton]

2. Approval No. PP-JAD-NZ-0008-1. TAPS NA 12522.

November 2020. BY10001

To be updated [Nadine Mackay]



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