

Package leaflet: Information for the user

Jadelle sine inserter 2 x 75 mg implants

Levonorgestrel

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Jadelle implants are and what they are used for
2. What you need to know before you use Jadelle implants
3. How to use Jadelle implants
4. Possible side effects
5. How to store Jadelle implants
6. Contents of the pack and other information

1. What Jadelle implants are and what they are used for

Jadelle implants are used for the prevention of pregnancy (contraception). The implants consist of two thin, flexible rods made of a rubber-like material, that are inserted by a minor surgical procedure just beneath the skin on the inside of your upper arm.

The implants slowly release a small amount of the hormone levonorgestrel, which is one of the active ingredients in many oral contraceptives. Jadelle implants are long-acting and are effective for up to five years. Immediately after insertion, low doses of the hormone start to be released continuously into your body.

Jadelle implants work by a combination of factors. The most important of these are prevention of regular egg release and thickening of the cervical mucus, making it more difficult for sperm to reach the egg.

Children and adolescents

Jadelle implants are not indicated for use before the first menstrual bleeding (menarche).

2. What you need to know before you use Jadelle implants

General notes

Before you decide to use Jadelle implants or any other contraceptive method, you should compare it to other available methods. If you want to learn more about other methods, ask your doctor or nurse. One of these other methods may be better for you than Jadelle implants. Each woman who considers using Jadelle implants should understand the benefits and risks of using this contraceptive method compared with other methods. This leaflet will give you much of the information you will need to make this decision but you will still need to discuss the matter thoroughly with your doctor. You should discuss the information provided in this leaflet, when choosing whether to use Jadelle implants and on check-up visits. Follow your doctor's advice with regard to check-ups while using Jadelle implants.

Some women should not use Jadelle implants. To find out whether you are one of them, talk to your doctor or nurse and read the sections entitled: "Do not use Jadelle implants" and "Warnings and precautions".

Some women who use Jadelle implants will experience side effects. You should know the warning signs. To learn about them, talk to your doctor or nurse and read the sections below entitled "Warnings and precautions" and "Possible side effects".

Contraceptive effectiveness of Jadelle implants

Jadelle implants are among the most effective reversible contraceptive methods. However, no contraceptive is 100 percent effective. The average annual pregnancy rate for Jadelle implants over a 5-year period is less than 1%. This means less than one pregnancy for every 100 women during the first year of use. After the 5th year of use, the contraceptive efficacy decreases, and consequently Jadelle implants must not be used for more than 5 years.

Protection against HIV infection or other sexually transmitted diseases

Jadelle implants do not protect against HIV infection (AIDS) or other sexually transmitted diseases.

Do NOT use Jadelle implants if you:

- are allergic to levonorgestrel or any of the other ingredients in Jadelle implants (listed in section 6)
- have abnormal vaginal bleeding
- have, or are suspected of having, breast cancer or cancer of the lining of the womb
- have, or have ever had, severe illness involving your liver, as long as your liver is not working properly again as judged by laboratory
- have, or have ever had, a liver tumour (benign or malignant)
- have a blood clot in a blood vessel (thrombosis) in, for instance, your leg, lung or eye.

Warnings and precautions

Talk to your doctor before using or while you are using Jadelle implants, if any of the following symptoms occur:

- migraines or increase in the frequency of migraine attacks
- persistent headaches or problems with vision, particularly if you are overweight or have recently gained weight
- sudden headaches or vomiting, dizziness or fainting, disturbances of vision or speech, weakness, or numbness in an arm or leg
- pain in the calf of the leg or unusual swelling of arms or legs
- sharp pain in the chest or sudden difficulty in breathing, or coughing blood
- unbearable pain or a feeling of pressure in the chest
- severe abdominal pain or tenderness in the abdominal area
- suspect you may be pregnant
- heavy vaginal bleeding

- skin or eyes become yellow
- lump or lumps in the breast
- pain, pus or bleeding at the insertion site of the implants
- sleeping problems, weakness, lack of energy, tiredness or mood swings
- implant is expelled
- fluid retention.

If you, or someone in your family, have certain diseases, you must discuss with your doctor if you should have the implants. Tell the doctor if you:

- have had an ectopic pregnancy (see section on “Pregnancy, breast-feeding and fertility”)
- or someone in your family has a history of formation of blood clots (thrombosis) or a blood clotting (coagulation) disorder, stroke, heart attack, high blood pressure, very high lipid or cholesterol levels or coronary artery disease (see section “Blood clots (thrombosis)”)
- have or have had migraines or frequent headaches
- have or have had a lump or lumps in your breast, mastopathy or an abnormal mammogram (breast X-ray) or someone in your family has had breast cancer
- have problems with your gall bladder, liver disorders or a kidney disease
- have diabetes
- have depression (see section “Psychiatric disorders”)
- have impaired hearing due to otosclerosis
- have had itchy, red hives or small bumps (herpes gestationis) during pregnancy.

Your doctor may decide that you will be able to use Jadelle implants, even if any of the above applies to you.

Blood clots (thrombosis)

As with oral contraceptives, there have been reports of blood clots, heart attacks and strokes in connection with the use of levonorgestrel implants.

If you develop a clot, for instance in your leg, lung or eye, Jadelle implants must be removed.

If you are bedridden after **surgery**, or have limited movement for a long time because of an illness or an accident, the risk of blood clots may increase. In that case, your doctor may decide to remove the Jadelle implants.

Psychiatric disorders

Some women using hormonal contraceptives including Jadelle have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

Blood pressure

Even though studies have not shown a considerable increase in blood pressure in users of Jadelle implants, blood pressure may still increase in some women. You should therefore have your blood pressure checked regularly whilst the implants are present.

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 Jadelle implants should be removed.

Breast cancer

Do not use the implants if you have, or are suspected of having, breast cancer. Users of combined oral contraceptives have been found to have a slightly increased (1.24 times the normal) risk of breast cancer. The risk of having breast cancer diagnosed in progestin-only contraceptive users, such as Jadelle, is possibly of a similar magnitude to that associated with combined oral contraceptives.

If you have benign lumps in your breast, fibrous (tough) breast tissue or an abnormal mammogram, or if you have a family history of breast cancer, your doctor should follow your condition carefully.

Increased pressure around the brain (intracranial pressure)

Increased pressure around the brain has been reported rarely in users of levonorgestrel implants. Contact your doctor if you experience frequent, severe or persistent headaches or have problems with your vision.

Enlarged ovarian follicles (ovarian cysts)

These may occur in some women with Jadelle implants. Such follicles will be detected in a physical examination and usually disappear on their own. In rare cases, however, they may twist or rupture, causing abdominal pain, and may require surgery. If you feel any pain or discomfort, contact your doctor.

Children and adolescents

The safety and effectiveness of Jadelle implants have not been established in females below 18 years.

Other medicines and Jadelle implants

Always tell your healthcare professional if you are taking, have recently taken or might take any other medicines. Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist from whom you get the medicine) that you are using Jadelle. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long (see section on “Extra contraceptive precautions”), or, whether the use of another medicine you need must be changed.

Some medicines:

- can have an influence on the blood levels of Jadelle
- can make Jadelle less effective in preventing pregnancy
- can cause unexpected bleeding.

These include:

- medicines used for the treatment of:
 - epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate)
 - tuberculosis (e.g. rifampicin)
 - HIV and Hepatitis C Virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors, e.g. efavirenz, nelfinavir, ritonavir, darunavir/ritonavir, (fos)amprenavir/ritonavir, lopinavir/ritonavir, and tipranavir/ritonavir, nevirapine, indinavir and atazanavir/ritonavir, etravirene).
 - fungal infections (griseofulvin, azole antifungals, e.g. itraconazole, voriconazole, fluconazole).
 - pulmonary artery hypertension (e. g. bosentan)
 - bacterial infections (macrolide antibiotics, e.g. clarithromycin, erythromycin)
 - certain heart diseases, high blood pressure (calcium channel blockers, e.g. verapamil, diltiazem)
- the herbal remedy St. John’s wort
- grapefruit juice

Mid-cycle bleeding and unintended pregnancies have been reported. You need to take additional reliable non-hormonal contraceptive precautions such as condoms while you are taking the other medicine and for **28 days** afterwards. Read carefully the section on “Extra contraceptive precautions”.

In case you have a long-term treatment using the medicines mentioned above, Jadelle implants should be removed and you should use non-hormonal contraception instead.

Jadelle may influence the effect of other medicines. Accordingly, the concentration of these other medicines in the blood and tissues may either increase (e. g. cyclosporine, a medicine used to prevent rejection of transplanted organs) or decrease (e. g. lamotrigine, a medicine used to treat epilepsy).

Laboratory tests

If you need a blood test or other laboratory tests tell your doctor or the laboratory staff that you are using Jadelle implants because these can affect the results of some tests.

Pregnancy, breast-feeding and fertility

Pregnancy

Jadelle implants must not be used during an existing or suspected pregnancy.

Ectopic pregnancy has sometimes occurred in users of other levonorgestrel implants.

Symptoms of ectopic pregnancy include:

- spotting (a small amount of blood loss)
- cramping abdominal pain

These usually begin shortly after the first missed period. Contact your doctor if you miss a period or have abdominal pain.

If, after the insertion of the implants, you first have a regular bleed and then your period is more than 2 weeks late, you should make sure that you are not pregnant.

If you become pregnant with Jadelle implants in place, you must have the implants removed. There are no studies available for Jadelle regarding an effect on the baby if used before or during pregnancy. However, contraceptive pills containing levonorgestrel used prior or during pregnancy have not caused harmful effects on the baby.

If you want to become pregnant Jadelle implants can be removed at any time by your healthcare professional (see section 3 “When should Jadelle implants be removed?”), after which pregnancy may be possible.

Breast-feeding

If you are breast-feeding and want to use these implants, you should discuss this with your doctor. Whilst levonorgestrel (the hormone in Jadelle) passes into breast milk, this does not have any negative effect on the growth and development of your baby. The quality and quantity of your breast milk is not affected.

Fertility

Your usual level of fertility will return after the implants are removed.

Driving and using machines

Jadelle implants have no influence on ability to drive or use machines.

3. How to use Jadelle implants

Jadelle implants are different from other contraceptive methods. They must be inserted and removed by a healthcare professional familiar with the minor surgical procedure. Some doctors have more experience than others in inserting and removing these implants. Discuss with your doctor or nurse to find out whether he/she is familiar with the insertion and removal of Jadelle implants and feels that he/she masters the procedures.

Before inserting the implants your doctor/healthcare professional will:

- ask you about your medical history
- perform a physical examination
- make sure that you are not pregnant.

Placement of Jadelle implants

Jadelle implants should be placed within seven days from the start of your menstrual bleed (your monthly period). In this case you will not need to take any additional contraceptive precautions.

If insertion is done after the 7th day (from the first day of bleeding) you will have to use other non-hormonal contraception e.g. condoms for at least the next 7 days. Read carefully the section on "Extra contraceptive precautions".

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

Jadelle implants should preferably be inserted on the day after you have taken the last active tablet of your combined oral contraceptive but at the latest on the day after the 7th day of the tablet free interval or placebo tablet.

If you have previously used a vaginal ring or a transdermal patch, Jadelle should preferably be inserted on the day of removal of the last ring or patch of a cycle pack, but at the latest when the application of the next ring or patch would have been due.

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

Jadelle implants may be inserted

- on any day if you have previously taken the minipill,
- on any day once your previous implant or IUS has been removed,
- when the next injection would have been due.

Use of Jadelle after giving birth, or after miscarriage or abortion

- If you have given birth and want to start using Jadelle, the implants may be inserted immediately after childbirth.
- If Jadelle is inserted within 3 weeks of delivery, you will not need other contraceptive precautions.
- If Jadelle is inserted later than 3 weeks after giving birth, your doctor will make sure that you are not pregnant, and you must use other non-hormonal methods of contraception for a minimum of 7 days after the insertion.
- If you have just had a miscarriage or an abortion and you want to start using Jadelle, the implants can be inserted immediately. Your doctor will tell you more about this.

Procedure

1. The doctor/healthcare professional will insert the two thin Jadelle implants just beneath the skin on the inside of your upper arm. If you are right-handed, usually your left arm is used, and if you are left-handed, your right arm is used.
2. A small cut will be made to insert the implants, to do this a local anaesthetic will be used at the insertion site.
3. The implants are placed underneath the skin, one at a time, with a separate instrument (trocar). Since the insertion site is anaesthetised, you should not feel any pain.
4. After the procedure, the insertion site will be closed with skin tape and bandaged. Keep the wound dry and bandaged for 3 days. Do not bruise the insertion site during this time or lift anything heavy with that arm.

There may be some discolouration, bruising and 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 temporary pain, discomfort or itching.

The following skin reactions have been reported in connection with the insertion of other similar levonorgestrel implants:

- scarring, blistering, shedding of skin, ulceration, tingling and numbness.

Talk to your doctor if you are worried – see also section 4.

Expulsion and displacement of implant

It is possible that an implant is expelled before the incision in your arm has healed, especially if the implants have been inserted very near the skin surface or too close to the incision or if the implant site is infected. If this happens contact your doctor because an expelled implant must always be replaced with a new, sterile implant.

You also need to take additional reliable non-hormonal contraceptive precautions such as condoms, until you have seen your doctor. Read carefully the section on “Extra contraceptive precautions”.

The implant may move position in your arm. This has been reported infrequently, however you may feel pain or discomfort. If you feel the implant has moved, contact your doctor.

Extra contraceptive precautions

If you need extra contraceptive precautions

- use reliable non-hormonal contraception, such as condoms or
- do not have sex.

Do not use the rhythm or temperature method as additional contraceptive precautions. Changes in body temperature and cervical mucus that normally take place during the menstrual cycle may not occur during the use of Jadelle implants.

When you should see your healthcare professional

After some time has elapsed from the insertion of the implants, your doctor/healthcare professional 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 to go for check-ups.

When should Jadelle implants be removed?

You can decide to have your Jadelle implants removed at any time, after which pregnancy is possible. Therefore, 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.

Jadelle implants **must be removed at the end of 5 years**. Do not put off removal after the 5 years have elapsed, as the implants will start to lose their effectiveness after that time. If you cannot see a doctor in time to have them removed at the end of the fifth year, you must take additional contraceptive precautions and have the implants removed as soon as possible. Read carefully the section on “Extra contraceptive precautions”.

If you want to continue using the implants, a new set can be inserted when the existing implants are removed.

If you weigh over 60 kg, your doctor may recommend that the implants are removed and replaced after 4 years of use rather than wait for the 5th year.

Removal procedure for Jadelle implants

The removal of Jadelle implants may be more difficult than their insertion. It may take longer and involve more pain. It may leave scars – a risk that does not exist with most other contraceptive methods.

1. As the implants are located beneath the skin on the inside of your upper arm, they must be removed by a doctor. Do not try to remove them yourself.
2. The implant site will be anaesthetised and a small cut will be made in the skin.
3. After the removal, keep the wound clean, dry and bandaged for 3 to 5 days or until the skin has healed. Bruising may occur at the site following removal. If the implants have been placed too deep, they may be more difficult to remove.

If both implants cannot be removed at the first attempt, you will need to see the doctor again for a new attempt. You must use another method of contraception until both implants have been removed.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The most frequently reported side effect is:

- irregularity of menstrual bleeding where periods may become prolonged (taking more days than usual), lighter or heavier, more frequent or less frequent, or spotting may occur between periods. In some women, periods may stop altogether.

Such bleeding irregularities occur in the majority of users during the first year and often reduce with continuing use of Jadelle implants. Despite the increased number of bleeding days, monthly blood loss is usually no greater than from normal menstruation.

Blood sugar and fat (lipid) levels may also be altered during the use of these implants. Patients with diabetes or disorders of lipid metabolism should therefore be monitored closely during the use of these implants. Blood bilirubin levels reflecting liver function may rise at the start of using the implants.

If you wear **contact lenses**, you may have vision changes or you may no longer be able to wear your lenses. If this happens, you should contact your doctor.

The following side effects have been reported in clinical studies:

Very common side effects: may affect more than 1 in 10 woman

- headache, nervousness, dizziness
- feeling sick (nausea)
- cervical inflammation, vaginal discharge, itching of the external genitals, lower abdominal pain, breast pain
- weight gain

Common side effects: may affect up to 1 in 10 woman

- mood swings, depression, decreased sexual drive, pain during sexual intercourse
- migraine
- palpitation, chest pain
- high blood pressure, varicose veins
- difficulty in breathing
- abdominal discomfort
- bilirubin, which is produced by your liver, may rise (this will show up in blood tests)

- acne, irritation of the skin (*contact dermatitis*), hair loss, excessive hairiness, rash, itching, skin discolouration
- urinary tract symptoms
- vaginal inflammation, ovarian cysts, benign breast lumps, breast discharge
- pain or itching at the implant site, pain in general, tiredness, back pain
- weight loss

Uncommon side effects: may affect up to 1 in 100 people

- bruising or infection at the implant site

Rare side effects: may affect up to 1 in 1,000 people

- expulsion of implant (see section 3“Expulsion and displacement of implant”), arm pain, numbness, tingling and scarring, difficulty in removal of the implants, nerve damage in the arm associated with removal of the implant, darkening of the skin over the implant site

On rare occasions, ectopic pregnancies have been reported (see section 2 “Pregnancy, breast-feeding and fertility”).

Darkened skin areas (hyperpigmentation) occurred in users of other levonorgestrel implants.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Jadelle implants

Keep this medicine out of the sight and reach of children.

Jadelle implants must not be inserted after the expiry date which is stated on the packaging. The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What Jadelle implants contains

- The product consists of two implants to be inserted subdermally.
- The active substance is levonorgestrel. Each implant contains 75 mg levonorgestrel.
- The other ingredients are: polydimethylsiloxane, anhydrous colloidal silica.

What Jadelle implants looks like and contents of the pack

The set contains two flexible, sealed, white or off-white rod-like implants, about 43 mm in length and 2.5 mm in diameter.

The two sterile implants are packed into a bag made from specialist plastic/woven material. This pack is for single use only.

Marketing Authorisation Holder and Manufacturer

Bayer Oy
Pansiontie 47
20210 Turku

Levonorgestrel 75 mg implant
(without inserter)
(Bayer Oy), RH017

WHOPAR part 3
(Suppliers submission of the
SRA approved text)

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This leaflet was last revised in 02/2021

Patient Reminder Card for Jadelle sine inserter 2 x 75 mg implants

Period of use: 5 years

Batch No.

The implants were inserted by:

Telephone number of the doctor or nurse:

Date:

Next visit:

Remarks:
