PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

JADELLE® 2 x 75 mg

Levonorgestrel

Read all of this leaflet carefully before receiving JADELLE.
- Keep this leaflet; you may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.

What is in this leaflet

1. What JADELLE is and what it is used for

JADELLE is a long-acting (up to 5 years) progestin-only contraceptive preparation. The implants consist of two thin, flexible rods made of a rubber-like material, and they are inserted underneath the skin. JADELLE implants are intended to prevent pregnancy.

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

Do not use JADELLE:

- if you are hypersensitive (allergic) to JADELLE or any of the other ingredients of JADELLE,
- if you are pregnant or you think you might be pregnant

- if you are breastfeeding, for the first 6 weeks post-delivery (see "Pregnancy and breastfeeding and fertility")
- if you have a history of thrombosis (blood clot) in a blood vessel, for instance, your leg, lung, eye or heart,
- if you have a liver tumour or an acute liver disease, as diagnosed by your doctor.
- if you have or are suspected of having cancer of the breast or of the lining of the womb,
- if you have abnormal vaginal bleeding,

Before you decide to use JADELLE:

What you should know about JADELLE implants before you decide to use them:

Each woman who considers using JADELLE should understand the benefits and risks of this contraceptive method as compared with other methods. You will need to discuss the matter thoroughly with your doctor. Follow your doctor's advice with regard to check-ups while using JADELLE implants.

You can decide to have your JADELLE implants removed at any time. It may leave scars – a risk that does not exist with most other contraceptive methods.

JADELLE implants are two thin, flexible rods made of a rubber-like material, that are inserted during outpatient surgical procedure just beneath the skin on the inside of your upper arm. Immediately after the insertion of JADELLE implants, low doses of the hormone start to be released continuously into your body.

Pregnancy is prevented through a combination of factors. When JADELLE implants are removed, your previous fertility will resume.

Contraceptive effectiveness of JADELLE implants:

No contraceptive is 100 % 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 fifth year of use, the contraceptive efficacy decreases, and consequently JADELLE implants must not be used for more than five years.

Warnings and precautions

Take special care with JADELLE:

If any of the following symptoms occur while you are using JADELLE implants, consult your doctor.

- 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.
- You suspect you may be pregnant.
- Heavy vaginal bleeding.
- The skin or eyes become yellow.
- A lump or lumps in the breast.
- Pain, pus or bleeding at the insertion site of JADELLE implants.
- Sleeping problems, weakness, lack of energy, fatigue, and mood swings.
- An implant is expelled.
- Fluid retention.

If you are planning to receive JADELLE implants and have, or someone in your family has, certain diseases, you will have to discuss the use of JADELLE implants thoroughly with your doctor. Tell your doctor if anything in the list below applies to you:

- You have had an ectopic pregnancy.
- You or someone in your family has a history of thrombosis or a coagulation disorder, stroke, heart attack, high blood pressure, very high lipid or cholesterol levels or coronary artery disease.
- You have or have had migraines or frequent headaches.
- You have or have had a lump or lumps in your breast, any other disease of the breast (mastopathy) or an abnormal mammogram (breast X-ray) or someone in your family has had breast cancer.
- You have problems with your gall bladder, liver disorders or a kidney disease.
- You have diabetes.
- You have depression.
- You have impaired hearing due to otosclerosis (progressive deafness caused by overgrowth of the bone in the inner ear).
- You have had herpes gestationis (auto immune skin disease) during pregnancy.

Blood clots (thrombosis)

There have been reports of thrombosis, heart attacks and strokes. If you develop a thrombosis for instance in your leg, lung, eye or heart, 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 thrombosis 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

Blood pressure increases in some users. You should therefore have your blood pressure checked regularly while you are using JADELLE implants.

Breast cancer

If you have benign lumps in your breast or any other disease of the breast (mastopathy), 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 (idiopathic intracranial pressure)

Increased intracranial pressure (idiopathic intracranial hypertension) has been reported. Contact your doctor if you experience frequent, severe, or persistent headaches of have problems with your vision.

Enlarged ovarian follicles (ovarian cysts)

Enlarged ovarian follicles (ovarian cysts) may occur in women with JADELLE implants. Such follicles will be detected in a physical examination and usually disappear on their own. They may twist or rupture, causing abdominal pain, and may require surgery.

Protection against HIV infections or other sexually transmitted diseases

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

Other medicines and JADELLE

Always tell your doctor which medicines or herbal products you are already using. 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, etravirine).

- 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, you should consider using another method of contraception instead of JADELLE implants.

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).

Extra contraceptive precautions:

If you need extra contraceptive precautions

- do not have sex, or
- use reliable non-hormonal contraception, such as condoms, spermicide (preparation killing sperm) or a diaphragm (cap).

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.

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 and breastfeeding and fertility

Pregnancy

JADELLE should not be used if you are pregnant. Tell your doctor if you suspect you may be pregnant. If you are pregnant, JADELLE implants must be removed.

If after the insertion of JADELLE implants, you first have regular menses and then a period is six weeks or more late, you should make sure that you are not pregnant. If you are pregnant, JADELLE implants must be removed.

Ectopic pregnancy has sometimes occurred in users of other levonorgestrel implants. Symptoms of ectopic pregnancy include spotting and cramping abdominal pain, which usually begins shortly after the first missed period. You should contact your doctor if you miss a period or have abdominal pain.

Breastfeeding

If you are breastfeeding your infant, you should have JADELLE implants inserted only six (6) weeks after childbirth.

Fertility

The implant should be removed if you fall pregnant during treatment with JADELLE.

Driving and using machines

JADELLE may affect your ability to drive and use machines.

JADELLE contains

Polydimethylsiloxane elastomer, polydimethylsiloxane tubing and polysiloxane adhesive.

3. How to use JADELLE

How is JADELLE inserted:

Your doctor will insert the JADELLE implant just beneath the skin on the inside of your upper arm, using a minor surgical procedure. If you are right-handed, usually your left arm is used, and if you are left-handed, your right arm is used. Because a small cut has to be made to insert the implants, a local anaesthetic will be used at the site of insertion

After the procedure, the insertion site will be closed with skin tape 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. The gauze and bandage may be removed as soon as the cut has healed, normally after 3 to 5 days.

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. Occasional, an infection may occur or there may be temporary 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.

Talk to your doctor if you are worried – see also section on "Possible side effects".

Expulsion and displaced of JADELLE implant

It is possible that a JADELLE 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 need to take additional reliable non-hormonal contraceptive precautions until you have seen a doctor. See section on "Extra contraceptive precautions".
The implant may move position in your arm. This has been reported frequently; however, you may feel pain or discomfort. If you feel the implant has moved, contact your doctor

When should JADELLE implants be inserted

JADELLE implants should be inserted within seven days from the beginning of your menstrual period. In this case you will not need to take any additional contraceptive precautions. If insertion is done later than 7th day (from the first day of bleeding) you will have to use other, non-hormonal contraception for at least the next 7 days. Read carefully the section on "Extra contraceptive precautions".

Changing from combined oral contraceptives (COC)

JADELLE implants should preferably be inserted on the day after you take/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.

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

JADELLE 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 implants after giving birth:

If you have given birth but do not breastfeed and want to receive JADELLE implants, the implants may be inserted immediately after childbirth. If they are inserted within three weeks from delivery, you will not need other contraceptive precautions. If they are inserted later, the doctor will make sure that you are not pregnant, and you should use other non-hormonal methods of contraception for a minimum of seven days after the insertion.

Use of JADELLE implants after miscarriage or abortion:

If you have just had a miscarriage or an abortion and you want to use JADELLE implants, they can be inserted immediately. Your doctor will tell you more about this.

When should JADELLE implants be removed?

JADELLE implants must be removed at the end of five years. If you want to continue using JADELLE implants, a new set can be inserted when the implants are removed. If you do not wish to become pregnant, **you must start using another method of contraception immediately after the removal**. The contraceptive effect of JADELLE implants stops very quickly after they have been removed.

If you weigh over 60 kg, your doctor may recommend to you the removal and change of implants into new ones already after the fourth year of use.

How are JADELLE implants removed?

Because the implants are located beneath the skin on the inside of your upper arm, they have to be removed by a doctor. Do not try to remove them yourself.

4. Possible side effects

JADELLE can have side effects.

Not all side effects reported for JADELLE are included in this leaflet. Should your general health worsen while using JADELLE, please consult your doctor, pharmacist, or other health care professional for advice.

Irregularity of menstrual bleedings is the most frequent reported side effect with JADELLE implants. The symptoms vary. The 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. Often bleeding irregularities diminish 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 lipid (fat) levels may be altered during the use of JADELLE implants. Patients with diabetes or disorders of lipid metabolism should therefore be followed closely during the use of JADELLE implants. Blood bilirubin levels reflecting liver function may rise at the start of the use.

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

In addition, the following undesirable effects that may be associated with JADELLE implants have been reported in clinical studies:

Frequent side effects:

- Vaginal discharge, lower abdominal pain, cervical inflammation, breast tenderness.
- Itching of external genitals.
- Headache, dizziness, nervousness.

- Weight gain.
- Nausea (feeling sick).

Less frequent side effects:

- Vaginal inflammation, ovarian cysts.
- Urinary tract symptoms.
- Benign breast lumps, breast discharge.
- Acne, rash, itching or skin discolouration, hair loss, excessive hairiness.
- Pain or itching at the implant site.
- Fatigue, back pain and pain in general.
- Weight loss.
- Abdominal discomfort.
- Mood swings, decreased libido, depression.
- High blood pressure, palpitation, chest pain.
- Varicose veins.
- Difficulty in breathing.
- Migraine.

If you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist or health care provider.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. Alternatively, you can report to Bayer SafeTrack site (https://www.safetrack-public.bayer.com).
By reporting side effects, you can help provide more information on the safety of JADELLE.

5. How to store JADELLE

JADELLE is stored at or below 30 ºC in the original packs.

KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.

JADELLE implants must not be inserted after the expiry date printed on the packaging.

JADELLE implants must be removed within five years from insertion.

6. Contents of the pack and other information

What JADELLE contains

The active substance is levonorgestrel.
The other ingredients are polydimethylsiloxane elastomer, polydimethylsiloxane tubing and polysiloxane adhesive.

What JADELLE looks like and contents of the pack

The product consists of two soft, flexible, opaque or almost white sterile rod implants. The sealing plugs at both ends are not less than 0,5 mm in length. Total length is approximately 43 mm.

Preloaded
Two implants are preloaded inside a disposable applicator (inserter) and a separate plunger. The tip of the inserter is covered with a removable scalpel. The applicator, scalpel body and plunger are made of thermoplastic co-polyester. The scalpel blade is made of stainless steel. All components of the inserter are translucent, colourless, or yellowish, essentially free from visible flashes, cracks and impurities.

Sine inserter (disposable trocar)
The two implants are packed into a bag manufactured from a spunbonded polyethylene film.

The product is packed in a transparent thermoformed tray of amorphous thermoplastic polyester sealed with a coated, spunbonded polyethylene film.

Pack sizes: 1 X 10 sets of two subdermal implants or 1 X 1 set of two subdermal implants.

Holder of Certificate of Registration

Bayer (Pty) Ltd
Reg. No.: 1968/011192/07
27 Wrench Road
ISANDO
1609
Tel: +27 (0) 11 921 5911

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