

PART III: CONSUMER INFORMATION

Pr JAYDESS®

Levonorgestrel-releasing intrauterine system

This leaflet is Part III of a three-part "Product Monograph" published when JAYDESS was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about JAYDESS. Contact your healthcare professional or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

JAYDESS is used for the prevention of pregnancy (contraception) for up to 3 years.

What it does:

JAYDESS is an intrauterine system (IUS). Levonorgestrel is a hormone commonly used in combination oral contraceptives (the "Pill") and is similar to progesterone, a sex hormone produced naturally by the body. JAYDESS works by slowly releasing levonorgestrel into the uterus at a rate of approximately 14 µg per day after 24 days and is reduced to approximately 10 µg per day after 60 days. It then declines progressively to 5µg per day after three years. The mean dissolution rate of levonorgestrel is approximately 6 µg per day over the period of three years. This amount of levonorgestrel:

- reduces the normal monthly thickening of the lining of the uterus.
- thickens the cervical mucus which prevents passage of sperm through the cervical canal (opening to the uterus).

These effects of levonorgestrel prevent pregnancy.

JAYDESS contains a total of 13.5 mg of levonorgestrel, which is enough hormone to prevent pregnancy for up to 3 years.

JAYDESS does not contain any estrogen.

Clinical trials found that there was less than 1 pregnancy per year for every 100 women using JAYDESS.

Other Ways to Prevent Pregnancy

Other methods of birth control are available to you. When used properly, other methods of birth control are effective enough for many women.

The following table gives typical pregnancy rates for various forms of birth control, including no birth control. The reported

rates represent the number of women out of 100 who would become pregnant within the first year of use.

Reported Pregnancies per 100 Women Within the First Year of Use

| | |
|---|-------------|
| Hormonal Intrauterine system (IUS) | less than 1 |
| Copper Intrauterine device (IUD) | less than 1 |
| Progesterone Injection | 6 |
| Combined hormonal contraceptive (pill, patch or ring) | 9 |
| Diaphragm | 12 |
| Male condom | 18 |
| Female condom | 21 |
| Sponge, spermicide | 12-28 |
| Withdrawal method | 22 |
| Natural family planning | 24 |
| No birth control | 85 |

The pregnancy rates listed in the table vary widely. This is because of differences in how carefully and regularly people use each method of birth control. Regular users may have lower pregnancy rates. Others may expect pregnancy rates in the middle ranges. This does not apply to IUDs because they are placed in the uterus and do not depend on user compliance.

When it should not be used:

JAYDESS is not suitable for every woman. In a small number of women, serious side effects may occur. Your healthcare professional can advise you if you have any conditions that would pose a risk to you. The use of JAYDESS should always be supervised by your healthcare professional. You should not use JAYDESS if you:

- have any allergies to the hormone levonorgestrel, or to any of the other ingredients of JAYDESS, or to components of the container (see the sections in this leaflet titled "What the medicinal ingredient is" and "What the nonmedicinal ingredients are")
- are pregnant or if you suspect you may be pregnant
- currently have pelvic inflammatory disease (PID) or have had recurrent PID (see the paragraph in this leaflet titled "Infections")
- have an infection of your lower genital tract, ie, vagina and/or cervix (neck of the womb), until the infection is controlled
- had an infection of the uterus (womb) after delivering a baby
- have bleeding from the vagina that has not been explained
- have a condition of the uterus that distorts the uterine cavity, such as large fibroids
 - have cell abnormalities in the cervix (your healthcare professional can tell you if you have this)

- have a known or suspected progestogen-dependent tumour, including breast cancer
- have liver disease or liver tumour
- have had an infection of the uterus (womb) after having an abortion during the past 3 months
- have cancer of the uterus or the cervix (uterine or cervical malignancy)
 - have a previously placed intrauterine device (IUD) that has not been removed
- have pregnancy related tumours
- have bacterial endocarditis (an infection of the heart valves or lining of the heart)
- have a history of blood clots (thrombosis)
- have a history of migraine, dizziness or blurred vision
- have severe headaches
- have or have had jaundice (a yellowing of the skin, whites of the eyes and/or nails)
- are diabetic or have a family history of diabetes, have high blood pressure or abnormal blood lipid levels
- you smoke
- have a family history of blood clots, heart attacks, or strokes

What the medicinal ingredient is:

levonorgestrel

What the nonmedicinal ingredients are:

Barium sulphate, iron oxide, polydimethylsiloxane, polyethylene, silica, silver

What dosage forms it comes in:

Each JAYDESS (levonorgestrel-releasing intrauterine system (13.5 mg)) is packaged with EvoInserter, an insertion device, and contains 13.5 mg of levonorgestrel to deliver up to 14 µg per day after 24 days and is reduced to approximately 10 µg per day after 60 days. It then declines progressively to 5µg per day after three years, with a mean rate of approximately 6 µg per day over 3 years.

If you see a different healthcare professional, inform him/her that you are using JAYDESS. You should inform your healthcare professional if you are scheduled for Magnetic Resonance Imaging (MRI), since JAYDESS can be safely scanned with MRI under most standard conditions.

Tell your healthcare professional if you are scheduled for any laboratory tests, since certain tests may be affected by hormonal contraceptives. Also, tell your healthcare professional if you are scheduled for surgery requiring prolonged bed rest.

JAYDESS should be used only under the supervision of a healthcare professional, with regular follow-up to identify side effects associated with its use. Your visits may include a blood pressure check, a breast exam, an abdominal exam and a pelvic exam, including a Pap smear. Visit your healthcare professional 4 to 12 weeks after the initial examination. Afterward, visit your healthcare professional at least once a year. Use JAYDESS only on the advice of your healthcare professional and carefully follow all directions given to you. Otherwise, you may become pregnant.

If you and your healthcare professional decide that, for you, the benefits of JAYDESS outweigh the risks, you should be aware of the following:

The Risks of Using JAYDESS

1. Diabetes

In diabetic users of JAYDESS, the blood glucose concentration should be closely monitored.

2. Infections

There is an increased risk of a serious pelvic infection called pelvic inflammatory disease (PID) in the first three weeks after placement of an intrauterine system or device. Other known risk factors include multiple sexual partners, frequent intercourse, and young age. PID can cause serious problems such as infertility, ectopic pregnancy, or constant pelvic pain. PID is usually treated with antibiotics; however, more serious cases of PID may require surgery. Tell your healthcare professional right away if you have any of these signs of PID: long-lasting or heavy bleeding, unusual vaginal discharge, low abdominal (stomach area) pain, painful sex, chills or fever.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- Hormonal Contraceptives including JAYDESS DO NOT PROTECT against Sexually Transmitted Infections (STIs) including HIV/AIDS. For protection against STIs, it is advisable to use latex or polyurethane condoms IN COMBINATION WITH JAYDESS.
- **Cigarette smoking increases the risk of serious adverse effects on the heart and blood vessels. Women should be counseled not to smoke.**
- **JAYDESS may penetrate or perforate (punch a hole) in the wall of the uterus.**

BEFORE you use JAYDESS talk to your healthcare professional or pharmacist if you have or have had any of the following conditions:

- are breast-feeding
- have given birth in the last 36 weeks
- have had a stroke, heart attack or any heart problems.
- have an abnormality of your heart or if you have any problem with your heart valves

3. Ectopic Pregnancy

Ectopic pregnancy (development of a fertilized egg outside the uterus) is possible when using JAYDESS, as it is in women using no contraception. However, if you accidentally become pregnant while using JAYDESS, an ectopic pregnancy is more likely. Ectopic pregnancy is a serious condition. Therefore, you should tell your healthcare professional if you have lower abdominal pain, especially if you have missed a period and/or have unexpected bleeding, since these can be signs of an ectopic pregnancy.

4. Cysts on the Ovary

Cysts on the ovary commonly occur in women using JAYDESS. These cysts usually disappear on their own and within a few months. However, cysts can sometimes cause pain and may need medical attention.

5. Uterine Perforations

Most often during placement, JAYDESS may penetrate or perforate (punch a hole in) the wall of the uterus, but this is uncommon. If this happens, JAYDESS must be removed.

The risk of perforation is higher in women who are breastfeeding at the time of JAYDESS placement and/or when JAYDESS is placed up to 36 weeks after delivery. The risk of perforation may be increased in women with an abnormally shaped uterus or with the uterus fixed and leaning backwards.

6. Use While Breast Feeding

Small quantities of levonorgestrel, the medicinal ingredient in JAYDESS, have been found in the milk of breast-feeding women using another LNG-releasing IUS. However, there does not appear to be a detrimental effect on growth or development of breast-fed infants whose mothers started using the product six weeks after delivery. Levonorgestrel does not appear to affect the amount or the quality of breast milk. You can use JAYDESS during breast-feeding. However, isolated cases of decreased milk production have been reported among women using JAYDESS.

7. Use in Pregnancy

If you become pregnant with JAYDESS in place, you should have it removed as soon as possible. If it is left in place during pregnancy, the chances of having a miscarriage or premature delivery increase. The effect of levonorgestrel on a developing infant is not well known, and therefore a detrimental effect cannot be completely ruled out. Removal of JAYDESS or probing of the uterus may result in spontaneous abortion. You should check with your healthcare professional about risks to your unborn child.

8. Use After Pregnancy and Abortion

Following childbirth, JAYDESS should be placed only after the womb has returned to its normal size, and not earlier than 6 weeks after delivery.

JAYDESS can be placed immediately after a first trimester abortion. If an abortion takes place in the second trimester, placement of JAYDESS should be delayed for 6 weeks or until the uterus has returned to normal size.

9. Pregnancy After Stopping JAYDESS

If you wish to become pregnant, ask your healthcare professional to remove JAYDESS. Your usual level of fertility should return soon after the system is removed. Approximately 86% of women wishing to become pregnant conceive within 12 months after removal of the system.

10. Broken JAYDESS

JAYDESS may break, most often during a difficult removal. Broken pieces must be found and removed. Surgery may be needed to do this.

Driving or Using Machines

The effect of JAYDESS on the ability to drive or to use machines has not been studied. Do not drive or use machines until you know how you react to JAYDESS.

How Will JAYDESS Affect My Periods?

JAYDESS may affect your menstrual cycle. It can change your menstrual periods so that you have spotting (a small amount of bleeding), shorter or longer periods, lighter or heavier bleeding, or no bleeding at all.

Many women have frequent spotting or light bleeding in addition to their periods for the first 3-6 months after they have JAYDESS placed. Some women may have heavy or prolonged bleeding during this time. Please inform your healthcare professional, especially if this persists.

Overall, you are likely to have a gradual reduction in the amount and number of days of bleeding each month. Some women eventually find that periods stop altogether.

When JAYDESS is removed, periods soon return to normal.

What if I Stop Having Periods?

Over time, your menstrual period may gradually disappear when using JAYDESS. This is because of the effect of the hormone on the lining of the uterus. The normal monthly thickening of the uterine lining with blood does not happen; therefore, there is little or no bleeding, as happens during a usual menstrual period. It does not necessarily mean you have reached menopause or are pregnant.

If, however, you are having regular menstrual periods and then do not have one for 6 weeks or longer, it is possible that you may be pregnant. You should speak to your healthcare professional.

INTERACTIONS WITH THIS MEDICATION

Please inform your healthcare professional or pharmacist if you are taking or have recently taken any other drugs or herbal products, even those without a prescription.

Hormonal contraceptives may become less reliable if you are also taking drugs that affect the liver (such as primidone, barbiturates, phenytoin, carbamazepine, rifampicin, and griseofulvin) at the same time. The influence of these drugs on the reliability of JAYDESS has not been studied, but is unlikely since JAYDESS releases a very small amount of hormone and delivers the hormone inside the uterus.

The T-frame of JAYDESS contains barium sulphate, which makes it visible in X-ray examinations. JAYDESS also contains a small silver ring, which makes it visible during ultrasound examinations.

See also ABOUT THIS MEDICATION: When it should not be used, and SIDE EFFECTS AND WHAT TO DO ABOUT THEM.

PROPER USE OF THIS MEDICATION

Usual dose

What it looks like:



JAYDESS consists of a small, white, T-shaped frame made from soft, flexible plastic. The vertical and horizontal arms of the T are approximately 3 cm in length. The vertical arm is surrounded by a narrow, cylindrical shaped reservoir that contains levonorgestrel. Two fine plastic threads are attached to the tip of the vertical arm. These threads are intended to be used for removal of the system and also serve to check its

presence once it is in place. In addition, the vertical stem contains a silver ring located close to the horizontal arms, which is visible under ultrasound examination.

How is JAYDESS Placed?

Before JAYDESS is placed, you will have a pelvic examination to determine the position and size of your uterus. Your healthcare professional will place the thin flexible plastic tube of the insertion device containing JAYDESS into your uterus. At this point you may feel a little discomfort.

Once JAYDESS is in the correct position, your healthcare professional will withdraw the tube leaving the system in place in the uterus. Finally, your healthcare professional will trim the removal threads to a suitable length.

After placement you may feel some cramp-like menstrual pain; however, this usually disappears within a few days.

Most women find that the placement procedure causes minor discomfort; however, for some it may be more uncomfortable. If concerned, you may wish to discuss the need for a painkiller or local anesthetic with your healthcare professional. Some women may feel faint after JAYDESS is placed, but this feeling subsides after a short rest. The placement procedure may precipitate a seizure in epileptic patients.

It is uncommon, but part or all of JAYDESS may penetrate the wall of the uterus during placement and come to rest outside the uterus. If this happens the system must be removed.

When Should JAYDESS be Placed?

JAYDESS should be placed within seven days of starting your period. When replacing an existing system for a new one, it is not necessary to wait for your period.

How Long Does Placement Take?

The placement procedure usually takes a few minutes after your healthcare professional has completed the pelvic examination.

How Quickly Does JAYDESS Start to Work?

When JAYDESS is placed within seven days of starting your period, you will be protected from pregnancy immediately. However, it is best to wait 24 to 48 hours before having sexual intercourse in the event of general discomfort.

How Often Should I Have JAYDESS Checked?

You should have JAYDESS checked approximately 4 to 12 weeks after it is placed, again at 12 months and then once a year until it is removed. JAYDESS can stay in place for 3 years before it must be removed.

How Can I Check if JAYDESS is in Place?

After each menstrual period or about once a month, you should check by feeling if the threads are still in place. Your healthcare professional will show you how to do this. Do not pull on the threads as you may accidentally pull JAYDESS out.

If you cannot feel the threads, this may indicate that JAYDESS has fallen out or uterine perforation has occurred. See your healthcare professional and in the meantime, use another method of nonhormonal contraception. You should also see your healthcare professional if you can feel the lower end of JAYDESS itself.

Will JAYDESS Interfere With Sexual Intercourse?

During sexual intercourse, you or your partner should not be able to feel JAYDESS. If you can feel JAYDESS, or any pain or discomfort that you suspect may be caused by it, then you should not have sexual intercourse until you see your healthcare professional to verify it is still in the correct position.

The removal threads may be felt by your partner during intercourse.

Can Tampons be Used?

Use of sanitary pads is recommended. If tampons are used, you should change them with care so as not to pull the threads of JAYDESS.

Can JAYDESS Fall Out?

It is unlikely, but possible that JAYDESS can come out either completely or partially. If this happens, you are not protected against pregnancy.

An unusual increase in the amount of bleeding during your period might be a sign that this has happened. If you think JAYDESS has come out, use another method of nonhormonal contraception until you see your healthcare professional.

Removal of JAYDESS

JAYDESS should not be left in place for more than 3 years. You should see your healthcare professional when you want to have JAYDESS taken out. Removal of JAYDESS is usually very easy. However, you should be aware that you may become pregnant upon removal of JAYDESS if you have had sexual intercourse during the previous week.

Tell your healthcare professional if you have had sexual intercourse during the preceding week.

Missed Dose

If you wish to continue using JAYDESS after 3 years, your healthcare professional can place a new system after removing the old system. If the same JAYDESS system has been left in place for longer than 3 years, you may become pregnant.

Pregnancy should be ruled out before placement of a new system.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects with JAYDESS are more common during the first months after placement; they gradually decrease over time.

Menstrual bleeding irregularities are the most common side effects of JAYDESS during the first months after the system is placed, but these effects should decrease over time.

Very common side effects include: headache, abdominal/pelvic pain, acne/oily skin, bleeding changes including increased and decreased menstrual bleeding, spotting, oligomenorrhea (infrequent periods) and amenorrhea (absence of bleeding), ovarian cyst, vulvovaginitis (inflammation of the external genital organs or vagina).

Common side effects include: depressed mood/depression, migraine, nausea, alopecia (hair loss), upper genital tract infection, dysmenorrhea (painful menstruation), breast pain/discomfort, device expulsion (complete and partial), genital discharge.

Side effects of unknown frequencies include: device breakage.

Few women using JAYDESS after delivery have reported less milk production.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

| Symptom/ Effect | | Talk with your healthcare professional or pharmacist | | Get immediate medical help |
|-----------------|---|--|--------------|----------------------------|
| | | Only if severe | In all cases | |
| Common | Vaginal bleeding | ✓ | | |
| | Symptoms of vaginal infection, such as itching, or unusual or increased vaginal discharge | | ✓ | |
| | Headache | ✓ | | |
| | Abdominal pain/ pelvic pain | | ✓ | |

| SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM | | | | |
|--|---|--|--------------|----------------------------|
| Symptom/ Effect | | Talk with your healthcare professional or pharmacist | | Get immediate medical help |
| | | Only if severe | In all cases | |
| Common | Expulsion of JAYDESS | | ✓ | |
| | Migraine | ✓ | | |
| Un-common | Severe lower abdominal pain which may be together with bleeding, possibly meaning perforation of the uterus. | | ✓ | |
| | Persistent lower abdominal pain, together with fever or unusual discharge from the vagina, possibly meaning pelvic infection. | | ✓ | |
| | Persistent lower abdominal pain, together with nausea or breast tenderness and/or vaginal bleeding, possibly meaning intrauterine pregnancy, miscarriage, or ectopic pregnancy. | | ✓ | |
| | Dizziness | | ✓ | |
| Very Rare | Allergic reaction including itchiness, rash, swelling of face and lips, cheeks, tongue and/or throat | | | ✓ |

This is not a complete list of side effects. For any unexpected effects while taking JAYDESS, contact your healthcare professional or pharmacist.

HOW TO STORE IT

Store JAYDESS at room temperature (between 15°C and 30°C).

Keep out of reach of children and pets.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to:
 - Canada Vigilance Program
 - Health Canada
 - Postal Locator 1908C
 - Ottawa, Ontario
 - K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Website at www.healthcanada.gc.ca/medeffect.

Note: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For more information, please contact your health professional or pharmacist first, or Bayer Medical Information at 1-800-265-7382 or canada.medinfo@bayer.com.

This document plus the full product monograph, prepared for health professionals can be found at <http://www.bayer.ca> or by contacting the manufacturer at the above mentioned phone number and email address.

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