



Patient Information

This is Jaydess®

We hope that this brochure will answer your questions and concerns about Jaydess®.



What is Jaydess®?

Jaydess® is an intrauterine device consisting of a hormone capsule attached to a T-shaped frame made from a soft flexible plastic. The device is 30 mm long and is inserted inside the uterus using an inserter.

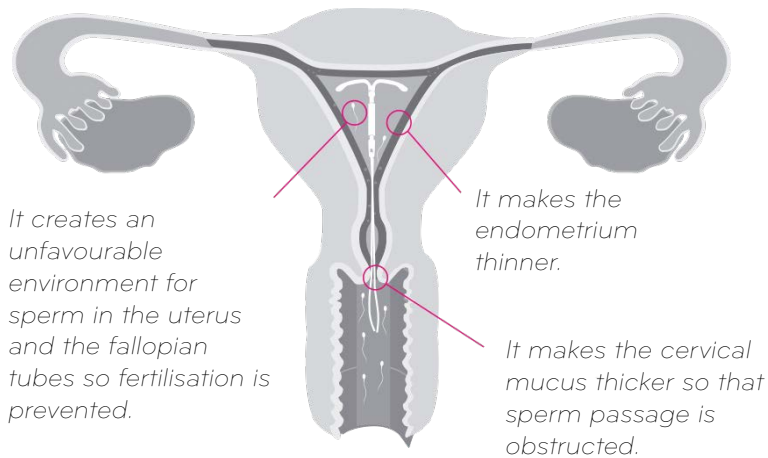
Jaydess® is the smallest three year hormone coil available and contains a low dose of hormone (6 µg levonorgestrel/24h). Your midwife/physician inserts it into your uterus, where it protects against unwanted pregnancy. By slowly releasing a low dose of the progestogen hormone levonorgestrel locally in the uterus, daily for up to 3 years, you will not have to think about daily, weekly or monthly administration.

How does Jaydess® work?

When Jaydess® is inserted in the uterus, a low dose of the hormone levonorgestrel is released slowly and continuously in the uterus on a daily basis, preventing pregnancy in three ways.

1. Jaydess makes the cervical mucus thick, so the passage of sperm is obstructed.
2. Jaydess affects endometrial growth. The mucous membrane becomes thin and infertile.
3. The device itself also contributes to an unfavourable environment for the sperm in the uterus and the fallopian tubes. Sperm motility is affected and fertilisation is prevented.

Jaydess® prevents pregnancy by a combination of several properties.



The only hormone in Jaydess® is levonorgestrel, a synthetic progestogen that is common in other hormonal contraceptives. Jaydess® contains no oestrogen.

How effective is Jaydess®?

Jaydess® is one of the most effective contraceptives. Jaydess® is more than 99% effective against pregnancy from the time it is inserted in the uterus until it is removed. Jaydess® is effective for up to 3 years.

How will levonorgestrel, the hormone in Jaydess®, affect my body?

Jaydess® works mainly locally in the uterus. It releases levonorgestrel in the uterus and only small amounts of the hormone enter the bloodstream. Levonorgestrel is a commonly used hormone in contraceptives. Jaydess® does not affect ovulation in the majority of women. This means that the ovaries continue to produce their own oestrogen. For more information about side effects when using Jaydess®, [see further down in this brochure](#) and the leaflet that is included with the package.

What is the purpose of the threads on Jaydess®?

The threads on Jaydess® are there so the midwife/physician can pull it out. Your midwife/physician will tell you how you can check the threads feel after the device is inserted. By feeling the threads, you can verify for yourself that Jaydess® is still in the correct position in the uterus, providing effective contraceptive protection. For further questions about the threads, do not hesitate to speak to your midwife/physician.

Your first days with Jaydess®

Important information you should know before getting Jaydess® inserted

How is Jaydess® inserted?

Once you have decided on Jaydess®, it can be inserted during your next visit to your midwife/physician. During a pelvic exam, they can simply insert Jaydess® into your uterus with a flexible inserter. After Jaydess® is inserted: the removal threads will be trimmed to a length of 2–3 cm.

What should I expect right after insertion?

Most women find that the insertion is relatively simple, but some may experience a little pain and dizziness during insertion. If you have severe pain or if the pain does not subside within a few weeks after insertion, you should contact your midwife/physician.

How quickly will Jaydess® protect against pregnancy?

If you get Jaydess® inserted within 7 days from the first day of your menstrual period, Jaydess® will provide immediate effective protection against pregnancy for up to 3 years. If Jaydess® is inserted at any other time during your menstrual cycle: you should protect yourself by also using condoms for the first 7 days. It is advisable to wait 24 hours prior to sexual intercourse after insertion of Jaydess®.

With Jaydess® you do not have to think about taking contraceptives daily, weekly or monthly.

Should I have a follow-up with a midwife/physician after getting Jaydess® inserted?

Your midwife/physician will decide whether you need to have a follow-up after insertion. You will also get information if you need to make additional visits.

Your first month with Jaydess®

Important information you should know before getting Jaydess® inserted

Are there any other reasons why I should contact my midwife/physician?

You should contact your midwife/physician if any of the following occurs:

- You have severe pain or heavy bleeding after insertion or if pain or bleeding continues for more than 5 weeks.
- You think you may be pregnant.
- You have persistent abdominal pain, fever or abnormal discharge.
- You or your partner feels pain or discomfort during sexual intercourse.
- You have changes in menstrual bleeding patterns (e.g. if you have little or no menstrual period and it suddenly becomes prolonged or profuse).
- You develop other medical problems, such as migraines/very severe headache, sudden vision problems, jaundice or hypertension.
- If you experience mood changes and symptoms of depression.

More things you should know when using Jaydess®

How will Jaydess® affect my menstrual bleeding pattern? Will I menstruate every month?

You will have less menstrual bleeding, both in the amount of bleeding and the number of days you bleed every month. The first 3–6 months after Jaydess® is inserted, you may have spotting or light bleeding. Some women may have longer or heavier bleeding during this period, but it does not mean that you will bleed every day. It may be helpful to write down how you bleed so you see that it gets better every subsequent day (a menstrual diary is included at the end of this brochure).

Talk to your midwife/physician if menstrual bleeding continues to be heavier than normal or if you are suddenly bleeding for more days than previously.

In some women, menstruation disappears completely when using Jaydess®. If you have not had any menstrual bleeding in the last 6 weeks and are worried that you may be pregnant, take a pregnancy test. If it is negative you do not need further tests, unless you have other symptoms that may indicate a pregnancy (for example, nausea, fatigue or tender breasts). If your menstrual bleeding stops while using Jaydess®, it should resume when Jaydess® is taken out.

Will Jaydess® affect my sex life?

When Jaydess® is in place in the uterus, it is unlikely that you or your partner will feel it during sexual intercourse.

Your future with Jaydess®

Should I keep track of my menstrual bleeding pattern?

Since you will probably notice a difference in your menstrual bleeding, it can be useful to keep track of your bleeding/spotting to help you and your midwife/physician monitor your experience with Jaydess®. At the end of this brochure, you will find a menstrual diary.

What if I decide to have children?

Jaydess® protects against pregnancy for up to 3 years, but you can always ask your midwife/physician to take it out. You can try to get pregnant as soon as your Jaydess® is removed. The majority of women in clinical studies who wished to become pregnant conceived within 1 year after Jaydess® was removed, which is the same rate as for women who are not using contraception.

If you want to get pregnant

Things to consider when planning a pregnancy

The Swedish National Food Agency (Livsmedelsverket) recommends an intake of 400 µg of folic acid every day starting one month before conception and during at least the first 12 weeks of pregnancy. This is to help prevent spina bifida in the baby. A sufficient amount of folic acid remains important throughout pregnancy, particularly for the mother's blood formation and for foetal development (Livsmedelsverket 2019).

FAQs

Can I use Jaydess® if I have not given birth?

Yes, but it is not the method of first choice for women who have not given birth due to limited clinical experience.

Can I use Jaydess® between births?

Yes. The earliest Jaydess® can be inserted is 6 weeks after giving birth and then it provides protection against pregnancy for up to 3 years. You can try to get pregnant as soon as your midwife/physician removes your Jaydess®.

Does Jaydess® offer protection against sexually transmitted diseases?

No. Jaydess® is used to protect against unwanted pregnancy and does not offer protection against sexually transmitted diseases, including HIV and AIDS. It is important that you use a condom to protect against STDs.

What will happen if I get a sexually transmitted disease?

If you think you have been infected with a sexually transmitted disease while using Jaydess[®], contact your midwife/physician. You should avoid sexual intercourse until you have gotten in touch with your health care provider.

What if I get pregnant while using Jaydess[®]?

The risk of getting pregnant while using Jaydess[®] is very small, but it can happen. The fact that you do not have menstrual bleeding when using Jaydess[®] does not usually mean that you are pregnant. If you do not get your menstrual period as expected and have other symptoms that may indicate a pregnancy (for example nausea, fatigue, tender breasts), you should speak to your midwife/physician right away. If you become pregnant, there is a 50% risk that the pregnancy is outside the uterus.

The following signs and symptoms may indicate a pregnancy outside the uterus:

- Your menstrual period has ended and you suddenly have persistent bleeding and stomach pain.
- You have severe or persistent pain in the lower abdomen.
- You have the normal symptoms of pregnancy but may also bleed and feel dizzy.

If you experience any of the above, you should speak to your midwife/physician right away.

Can I take Jaydess[®] out before it has been in place for 3 years?

Yes. You can ask your midwife/physician to remove Jaydess[®] at any time.

Can I use tampons while I have Jaydess[®]?

Yes, but be careful when you pull the tampon out so you don't pull on the threads that are attached to Jaydess[®].

Can Jaydess[®] "fall out"?

Jaydess[®] can come out partially or completely, but it is very unusual. If you believe your bleeding is heavier than normal, it may be a sign that Jaydess[®] has come out (partially or completely). If Jaydess[®] comes out, you are no longer protected against pregnancy. You should avoid sexual intercourse or use condoms and consult your midwife/physician.

Can an IUD cause weight gain?

Studies have shown that there is no difference in weight gain in women using an IUD compared with women using a contraceptive without any hormones (e.g. copper coil).

Why is there a silver ring on Jaydess[®]?

This enables health care professionals to distinguish Jaydess[®] from other coils when they do an ultrasound. The silver ring is nickel-free but you should tell your midwife/physician if you are allergic to silver.

What are the common side effects of Jaydess®?

As with any medication, you can experience some side effects with Jaydess®. Below is a list of the most common side effects women have reported when using Jaydess®. If you have additional questions, you can read more in the package leaflet or call your midwife/physician.

Very common (affect more than 1 in 10 users)

Headache, abdominal and pelvic pain, acne/oily skin, changes in bleeding patterns, ovarian cysts, inflammation of the external genitals or vagina.

Common (affect more than 1 in 100 users)

Depressed mood/depression, migraine, nausea, genital infection, painful menstruation, pain/discomfort in the breasts, device expulsion, hair loss, vaginal discharge.

Jaydess® Menstrual Diary

Please use the menstrual diary on the next page to keep track of any bleeding or spotting that may occur in the coming months. Keep in mind that every woman is unique and that your pattern of bleeding may vary.

Instructions:

- Mark with a dot (•) when you have spotting.
- Mark with an X when you have normal menses.
- Fill the entire box (n) when your menstrual bleeding is heavy.
- Leave the box blank when you are not bleeding.

Inform your practitioner at every appointment that you are using Jaydess®.

Jaydess®, intrauterine device, 13.5 mg levonorgestrel

Indications: Contraception. Side effects: headache, abdominal/pelvic pain, acne/oily skin, altered mood and changes in menstrual bleeding patterns. Warnings/caution: Jaydess® should be used with caution or removed, after consultation with the specialist, if one of the following conditions exists or arises for the first time: very severe headache, focal migraine with asymmetrical visual loss, jaundice, hypertension, stroke or heart attack. Women who are considering getting a Jaydess® device should be informed about the signs and symptoms, and the risk of ectopic pregnancy. Some women who use hormonal contraceptives have reported depression or mood changes. If you have mood changes, contact your midwife or doctor. For women who have not given birth, Jaydess® is not the contraceptive method of first choice since the clinical experience is limited. Contraceptive G02BA03. Rx. F. For more information, see the package leaflet and www.fass.se ▼ This medicinal product is subject to additional monitoring. SPC 2019-07-01



Bayer AB, Box 606, 169 26 Solna, tel 08-580 223 00

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