



Jaydess®▼

Questions and Answers



 jaydess.
13.5 MG INTRAUTERINE DELIVERY SYSTEM
LEVONORGESTREL

Welcome to Jaydess®

This booklet is only intended for direct distribution by a healthcare professional to women who have already been prescribed Jaydess®.

Further information can be found on www.medicines.ie.

Everyone has different priorities, and at this time in your life, getting pregnant may not be one of yours.

That's why you and your healthcare professional have decided on Jaydess®.

You probably have several questions about Jaydess®. This brochure will:

1. Introduce you to Jaydess®
2. Provide information on what to expect during your first months with Jaydess®
3. Answer frequently asked questions about Jaydess®

The facts about Jaydess®

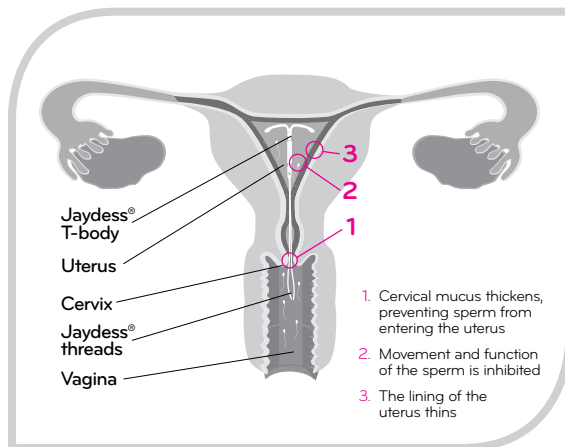
What is Jaydess®?

Jaydess® is an intrauterine system (IUS), a small T-shaped device made of soft, flexible plastic designed to prevent you from getting pregnant for up to 3 years. Jaydess® works without daily, weekly or monthly administration.¹

Jaydess®, the smallest IUS available,^{1,2} contains a low dose of hormone called levonorgestrel. Your healthcare professional places it in your uterus (womb), where it prevents pregnancy by slowly releasing a low dose of the hormone into the uterus.

How does Jaydess® work?

When Jaydess® is in place it works primarily where you need it, releasing a low dose of levonorgestrel slowly and continuously into the uterus, and preventing pregnancy in 3 ways. The cervical mucus thickens, which prevents sperm from entering the uterus. The movement and functioning of any sperm within the uterus is inhibited. The lining of the uterus also thins.¹



The only hormone in Jaydess® is levonorgestrel, a progestogen commonly found in other forms of hormonal contraception. Jaydess® does not contain an estrogen.¹

How effective is Jaydess®?

Jaydess® is one of the most effective methods of birth control.³ Jaydess® remains more than 99% effective from the time your healthcare professional places it in your uterus, until it is removed, which can be up to 3 years later.¹

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

Jaydess® is referred to as "mainly locally acting" because it works primarily where you need it to—in your uterus. It releases levonorgestrel into your uterus, and only very small amounts of the hormone enter your bloodstream.¹

Levonorgestrel is a commonly used and well-tolerated hormone in contraception. While using Jaydess®, ovulation (the release of an egg) is usually not affected.¹

For more information about common side effects associated with Jaydess®, please refer to the Patient Information Leaflet within the pack or else go to www.medicines.ie.

Your first few days with Jaydess®

Some important information you should know about starting with Jaydess®.

How is Jaydess® placed?

Once you and your doctor have decided on Jaydess®, it can be placed during a normal surgery visit. After a gynaecological examination, an instrument called a speculum is placed into the vagina, and the cervix may be cleaned with antiseptic. Your doctor then places Jaydess® in the uterus using a thin, flexible plastic tube. Local anesthesia may be applied to the cervix before Jaydess® is placed or pain relief may be advised by your doctor.

What should I expect immediately after placement?

Most women tolerate placement of Jaydess® well.³ However, you may experience pain and dizziness during or after placement, which will usually settle down quickly. If you have severe pain or if pain continues for more than a few weeks after placement, you should contact your healthcare professional.^{1,4}

What are the threads attached to Jaydess®?

The 2 threads allow your healthcare professional to remove Jaydess®.¹ Your healthcare professional may show you how to check that the threads are present. Being able to feel the threads can reassure you that Jaydess® is still in place and providing effective contraception. If you have any additional questions about the threads, talk to your healthcare professional.

How soon does Jaydess® start working?

If placed within 7 days of the start of your monthly period, Jaydess® immediately provides more than 99% efficacy and works for up to 3 years to prevent pregnancy.¹ However, it is advised to wait 24 hours after Jaydess® is placed before having sex.²

Should I follow up with my healthcare professional after Jaydess® has been placed?

You should visit your healthcare professional once in the first 4 to 6 weeks after having Jaydess® placed. After that, your healthcare professional will advise you about scheduling follow-up visits.¹ It is usually recommended that you visit your doctor on a yearly basis.

Are there other reasons to contact my healthcare professional?

In addition to visiting your healthcare professional once in the first 4 to 6 weeks after having Jaydess® placed, you should contact your healthcare professional if any of the following occurs⁴:

- You have severe pain or heavy bleeding after placement or if the pain or bleeding continues for more than a few weeks after placement
- You think you may be pregnant*
- You have persistent abdominal pain, fever, or unusual vaginal discharge
- There are sudden changes in your menstrual periods (for example, if you have little or no menstrual bleeding, then start having persistent or heavy bleeding or pain)
- You have other medical problems, such as migraines or exceptionally severe headaches, sudden problems with vision, jaundice, or high blood pressure

*Please see the section on pregnancy on page 11.

Here are some additional things you should know as you continue on with Jaydess®.

How will Jaydess® affect my bleeding pattern? Will I get a monthly period?

Overall, you are likely to have a gradual reduction in the amount and number of days of bleeding each month, leading to lighter and shorter periods. However, you may have some spotting or light bleeding in addition to your periods for the first 3 to 6 months after Jaydess® is placed. Some women may have heavy or prolonged bleeding during this time, but this does not mean you will bleed daily.⁴

Consult your healthcare professional if bleeding remains heavier than usual or if the bleeding becomes heavy after it has been light for a while.⁴

Among some women, periods may disappear altogether when using Jaydess®. If you have not had a period for 6 weeks and are concerned about pregnancy, then consider taking a pregnancy test. In case it's negative, there is no need to take another test unless you have other signs of pregnancy (e.g. sickness, tiredness or breast tenderness). If your monthly period does stop while on Jaydess®, it should return once Jaydess® is removed.⁴

Will Jaydess® interfere with sex?

Since Jaydess® is placed in the uterus, not the vagina, neither you nor your partner should feel Jaydess® during sexual intercourse.¹

Now that you know what to expect in the first few months after placement of Jaydess®, here is what you need to know for the next 3 years.

Should I keep track of my bleeding profile?

Because you may experience changes in your monthly period, keeping track of any bleeding or spotting may be helpful. This will help you and your healthcare professional monitor your experience with Jaydess®. There is a bleeding diary in the back of this brochure to help you get started.

What if I decide to have a baby?

Jaydess® prevents pregnancy for up to 3 years, but you can ask your healthcare professional to remove Jaydess® at any time if you want to have a baby. You may begin trying to become pregnant as soon as Jaydess® is removed.¹

In clinical trials, the majority of women who desired to become pregnant after removal of Jaydess® were able to do so within 1 year.¹ These rates were similar to those for women who had not used Jaydess®.⁵

Frequently asked questions

Does Jaydess® protect against sexually transmitted infections (STIs)?

No. Jaydess® is used for the prevention of pregnancy only and will not protect you from STIs, including HIV and AIDS.¹ It's important to be safe and protect yourself from STIs by using condoms.

What if I get an STI?

If you think you have an STI while using Jaydess®, contact your healthcare professional. You should avoid intercourse or use a barrier contraceptive (such as condoms) until you see your healthcare professional.

What if I get pregnant while using Jaydess®?

Although Jaydess® is over 99% effective, it is possible to become pregnant while using Jaydess®. Not having a period is not necessarily a sign of pregnancy while Jaydess® is in place; however, if you do not have your period and have other symptoms of pregnancy (for example, nausea, tiredness, breast tenderness), you should contact your healthcare professional.⁴ If you do become pregnant, there is a 50% risk that this pregnancy could be outside of the womb (ectopic pregnancy).¹

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

- Your menstrual periods have stopped and then you start having persistent bleeding or pain
- You have pain in your lower abdomen that is severe or persistent
- You have normal signs of pregnancy, but you also have bleeding and feel dizzy

If you experience any of the above, you should see your healthcare professional immediately.

Can I use Jaydess® between pregnancies?

Yes. Starting 6 weeks after delivery, (however it is recommended waiting 12 weeks) you can use Jaydess® for up to 3 years between pregnancies. When you want to have another baby, you can try to get pregnant as soon as Jaydess® is removed by your healthcare professional.¹

Frequently asked questions

Can I have Jaydess® removed before 3 years are up?

Yes, you can have it removed at any time by your healthcare professional.¹

Can I use tampons with Jaydess®?

Yes, but remove each tampon with care to ensure that you do not pull the Jaydess® threads.⁴

Can Jaydess® fall out?

While it is very unlikely, it is possible for Jaydess® to fall out completely or partially. If you notice your bleeding is heavier than usual during your period, it may be a sign that Jaydess® has fallen out either completely or partially. If Jaydess® falls out, you may not be protected from pregnancy. You should avoid intercourse or use a barrier contraceptive (such as condoms) and consult your healthcare professional.^{1,4}

Why does Jaydess® have a silver ring?

This allows your healthcare professional to distinguish Jaydess® from other intrauterine systems on ultrasound examination.¹ If you have allergies to silver, please notify your healthcare professional.

What are the side effects of Jaydess®?

Jaydess® was well tolerated in clinical trials. However, as with any drug, some women may experience side effects. If you have any further questions, please refer to the Patient Information Leaflet or ask your healthcare professional.

Where can I get more information?

We hope this brochure was helpful, but we understand that you may have additional questions. For more information and updates about Jaydess®, ask your healthcare professional or go to www.medicines.ie.

Jaydess® bleeding diary

Use this Jaydess® bleeding diary to keep track of any spotting or bleeding that may occur in the next few months. Please keep in mind that every woman's body is unique and your personal bleeding patterns may vary.

Instructions

- Mark a dot (•) when you are spotting
- Mark an (x) when your flow is normal
- Fill in the box (■) when your flow is heavy
- Leave the box blank when you are not bleeding

JAN	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
FEB	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
MAR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
APR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
MAY	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
JUN	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
JUL	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
AUG	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
SEP	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
OCT	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
NOV	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
DEC	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15

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16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professional are asked to report any suspected adverse reactions.

References: **1.** Jaydess® summary of product characteristics, www.medicines.ie. **2.** Nelson AL, Gemzell-Danielsson K, Borgatta L, Hauck B, Lynen R, Rosen K. User satisfaction, ease of placement, and discomfort during placement of two low-dose levonorgestrel contraceptive intrauterine systems (LNG-IUSs) in a multicenter, randomized, phase III study. *Obstetrics and Gynaecology*, November 2013. **3.** World Health Organization Department of Reproductive Health and Research (WHO/RHR) and Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs (CCP), Knowledge for Health Project. *Family Planning: A Global Handbook for Providers* (2011 update). Baltimore and Geneva: CCP and WHO, 2011. **4.** Jaydess® patient information leaflet, www.medicines.ie. **5.** The Practice Committee of the American Society for Reproductive Medicine. Diagnostic evaluation of the infertile female: a committee opinion. *Fertil Steril*. 2012;98(2):302-307.

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