

Package leaflet: Information for the user

Mirena 20 micrograms/24 hours intrauterine delivery system

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 pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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1. What Mirena is and what it is used for

Mirena is a T-shaped intrauterine delivery system (IUS) which after insertion releases the hormone levonorgestrel into the womb. The purpose of the T-body is to adjust the system to the shape of the womb. The white vertical arm of the T-body carries a drug reservoir containing levonorgestrel. Two brown removal threads are tied to the loop at the lower end of the vertical arm.

Mirena is used for prevention of pregnancy, heavy menstrual bleeding, menstrual pain, and as progestogen treatment during menopausal hormone replacement therapy.

Mirena contains levonorgestrel which can sometimes be used in the treatment of illnesses other than the ones mentioned in this leaflet. Ask your doctor, pharmacist or other healthcare professional for advice, if necessary, and always follow their instructions.

Children and adolescents

Mirena is not intended for use before the first menstrual bleeding.

2. What you need to know before you use Mirena

General notes

Before you can begin using Mirena, your doctor will ask you some questions about your personal health history and that of your close relatives.

In this leaflet, several situations are described where Mirena should be removed, or where the reliability of Mirena may be decreased. In such situations you should either not have sex or you should use non-hormonal contraception such as condoms or another barrier method. Do not use rhythm or temperature methods. These methods can be unreliable because Mirena alters the monthly changes of body temperature and cervical mucus.

Mirena, like other hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

Do not use Mirena:

- If you are pregnant or think you might be pregnant
- If you have tumors which depend on progestogen hormones to grow
- If you currently or recurrently have a pelvic inflammatory disease
- If you have an untreated infection of the cervix (neck of the womb)
- If you have an untreated lower genital tract infection
- If you have had an infection of the womb after delivery
- If you have had an infection of the womb after abortion or miscarriage during the past three months
- If you have a condition associated with increased susceptibility to infections
- If you have an untreated cell abnormality in the cervix
- If you have a malignant tumor in the womb or cervix
- If you have unexplained abnormal uterine bleeding
- If you have an abnormality of the womb or cervix, or fibroids that press on the cavity of the womb
- If you have an acute liver disease or liver tumor
- If you are allergic to levonorgestrel or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor before using Mirena.

Consult a doctor who may decide to continue using Mirena or remove the system if any of the following conditions exists or appears for the first time while using Mirena:

- Migraine, with visual disturbances or other symptoms which may be signs of a transient cerebral ischemia (temporary blockage of the blood supply to the brain)
- Exceptionally severe headache
- Jaundice (a yellowing of the skin, whites of the eyes, and/or nails)
- Marked increase in blood pressure
- Severe disease of arteries such as stroke or heart attack
- Sudden blood clot (thrombosis) in a vein or in the lungs (pulmonary embolism).

Symptoms or signs of thrombosis in the eye include unexplained partial or complete loss of vision, double vision, or some other unexplained visual disturbance.

There is not yet consensus whether varicose veins and superficial thrombophlebitis have a role in venous thrombosis.

Mirena may be used with caution in women who have congenital heart disease or valvular heart disease and are at risk of inflammation of the heart muscle.

In diabetic users of Mirena, the blood glucose concentration should be monitored. However, there is usually no need to adjust the treatment in diabetic users of Mirena.

Mirena is not the method of first choice for postmenopausal women with shrinking of the womb.

Use of sanitary pads is recommended. If you are using tampons or a menstrual cup, you should change them with care so as not to pull the threads of Mirena.

Breast cancer

Do not use this preparation 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. Since breast cancer is rare in women under 40 years of age, the increased risk of breast cancer is small compared with the overall breast cancer risk. The risk of having breast cancer diagnosed in progestin-only oral contraceptive users is possibly of a similar magnitude to that associated with combined oral contraceptives.

The risk of breast cancer is increased in menopausal women using hormone replacement therapy (tablets or a preparation applied on the skin). The risk is higher in users of the combination of estrogen and progestin than in users of estrogen only. The product information on the estrogen preparation used in the treatment must also be read through.

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

Medical examination and precautions

A physical examination before insertion may include a Pap smear if one has not been taken within three months, examination of the breasts and other tests, for example for infections, sexually transmitted diseases and pregnancy, as necessary. A gynecological examination should be performed to determine the position and size of the womb. Mirena is not suitable for use as an emergency contraceptive (postcoital contraceptive).

Effect on menstrual bleeding and bleeding disorders

In women of fertile age, Mirena reduces the number of bleeding days and the volume of menstrual bleeding gradually during the use in more than half the women, and in some women menstrual bleedings will stop altogether. If you have not had a period for six weeks, the possibility of pregnancy must be excluded. For further information on the effects of Mirena on menstrual bleeding, see section 3. "Can Mirena affect my menstrual cycle", "Is it abnormal to have no periods" and "How will I know if I'm pregnant".

Contact your doctor if you experience bleeding disorders during prolonged use or if bleeding starts after initiating estrogen replacement therapy.

24 hours intrauterine delivery system
(Bayer Oy) RH100

(suppliers submission of the
SRA approved text)

Infections

The insertion tube helps to protect Mirena from contamination with micro-organisms during the insertion, and the Mirena inserter has been designed to minimize the risk of infections. Despite this, there is an increased risk of pelvic infection immediately after insertion and during the first month after insertion. Pelvic infections in IUS users are often related to sexually transmitted diseases. The risk of infection is increased if the woman or her partner has several sexual partners. Pelvic infections must be treated promptly. Pelvic infection may impair fertility and increase the risk of a future extrauterine pregnancy (pregnancy outside the womb).

In extremely rare cases severe infection or sepsis (very severe infection which may be fatal) can occur shortly after insertion.

Mirena must be removed if there are recurrent pelvic infections or infections of the lining of the womb, or if an acute infection is severe or does not respond to treatment within a few days.

Consult a doctor without delay if you have persistent lower abdominal pain, fever, pain in conjunction with sexual intercourse, or abnormal bleeding. Severe pain or fever developing shortly after insertion may mean that you have a severe infection, which must be treated immediately.

Expulsion

The muscular contractions of the womb during menstruation may sometimes push the IUS out of place or expel it. This is more likely to occur if you are overweight at the time of the IUS insertion or have a history of heavy periods. If the IUS is out of place, it may not prevent pregnancy and therefore, the risk of pregnancy is increased. If the IUS is completely expelled, you are not protected against pregnancy anymore.

Possible symptoms of an expulsion are pain and abnormal bleeding but Mirena may also come out without you noticing it. As Mirena decreases menstrual flow, an increase in menstrual flow may be a sign of an expulsion.

It is recommended that you check with your finger that the removal threads are in place, for example while having a shower. See also section 3 "How to use Mirena" and "How can I tell whether Mirena is in place". If you have signs indicative of an expulsion or you cannot feel the threads, you need to use another contraceptive (such as condoms), and consult a healthcare professional.

Perforation

Penetration or perforation of the wall of the womb may occur, most often during insertion, although it may not be detected until sometime later. A Mirena which has become lodged outside the cavity of the womb has reduced contraceptive efficacy and must be removed as soon as possible. You may need surgery to have Mirena removed. The risk of perforation of the uterine wall is increased in breastfeeding women and in women who had a delivery up to 36 weeks before insertion. In women with the uterus fixed and leaning backwards (a poorly moving, backwards tilted womb), the risk of perforation by the IUS may be increased. If you suspect a perforation, seek prompt advice from a healthcare professional and explain that you have had Mirena inserted. Especially if they are not the person who inserted it.

Possible signs and symptoms of perforation may include:

- Severe pain resembling menstrual cramps, or pain that is more severe than expected

- Heavy bleeding (after insertion)
- Pain or bleeding which continues for more than a few weeks
- Sudden changes in your periods
- Pain during sex
- You can no longer feel the removal threads of Mirena (see section 3 "How can I tell whether Mirena is in place?)

Extrauterine pregnancy

It is very rare to become pregnant while using Mirena. However, if you become pregnant while using Mirena, the risk that you could carry the fetus outside of your womb (have an extrauterine pregnancy) is slightly increased. About 1 in 1,000 women correctly using Mirena have an extrauterine pregnancy per year. This rate is lower than in women not using any contraception (about 3 to 5 in 1,000 women). The risk is higher if you have previously had an extrauterine pregnancy, surgery on the tubes from the ovaries to the womb, or a pelvic infection. An extrauterine pregnancy is a serious condition which calls for immediate medical attention. The following symptoms could mean that you may have an extrauterine pregnancy and you should see your doctor immediately:

- Your menstrual periods have ceased and then you start having persistent bleeding or pain.
- You have vague or very bad pain in your lower abdomen.
- You have normal signs of pregnancy, but you also have bleeding and feel dizzy.

Faintness

Some women feel dizzy after Mirena is inserted. This is a normal physical response. Your doctor will tell you to rest for a while after you have had Mirena inserted.

Enlarged ovarian follicles (cells that surround a maturing egg in the ovary)

Since the efficacy of Mirena is mainly due to its local effect, ovulatory cycles with follicular rupture usually occur in women of fertile age. Sometimes degeneration of the follicle is delayed and the development of the follicle may continue. Most of these follicles give no symptoms, although some may be accompanied by pelvic pain or pain during intercourse. These enlarged follicles may require medical attention, but they usually disappear on their own.

Psychiatric disorders

Some women using hormonal contraceptives including Mirena 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.

Other medicines and Mirena

Since the mechanism of action of Mirena is mainly local, intake of other medicines is not believed to have a major effect on the contraceptive efficacy of Mirena. Tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Mirena must not be used if you are pregnant or think you may be pregnant.

It is very rare for a woman to become pregnant with Mirena in place. If Mirena comes out, you are no longer protected and must use another form of contraception until you see your doctor.

Some women may not have their periods while using Mirena. Not having a period is not necessarily a sign of pregnancy. If you do not have your period and have other symptoms of pregnancy (for example nausea, tiredness, breast tenderness), you should see your doctor for an examination and have a pregnancy test.

If you become pregnant with Mirena in place, you should contact your healthcare professional immediately to have Mirena removed. The removal may cause a miscarriage. However, if Mirena is left in place during pregnancy, not only is the risk of having a miscarriage higher, but also the risk of preterm labor. If Mirena cannot be removed, talk with your healthcare professional about the benefits and risks of continuing the pregnancy. If the pregnancy is continued, you will be closely monitored during your entire pregnancy and you should contact your doctor if you experience stomach cramps, pain in your stomach, or fever.

Mirena contains a hormone called levonorgestrel, and there have been isolated reports of effects on the genitalia of female babies if exposed to levonorgestrel while in the womb. Mirena can be used during breast-feeding. Levonorgestrel has been identified in small quantities in the breast milk of nursing women (0.1% of the dose is transferred to the infant). Hormonal contraceptives are not recommended as the method of first choice during breast-feeding, but progestogen-only methods are considered to comprise the next choice category after non-hormonal methods. There appears to be no negative effects on infant growth or development when using Mirena six weeks after delivery. Progestogen-only methods do not appear to affect the quality of breast milk.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

No known effects.

Mirena contains barium sulphate

The T-frame of Mirena contains barium sulphate, which makes it visible in X-ray examination.

3. How to use Mirena

How effective is Mirena?

The probability of failed contraceptive efficacy during the use of Mirena is about 0.2% in the first year of use. The risk of pregnancy may increase in case the IUS is displaced or it perforates the uterine wall (see section 2 "Medical examination and precautions").

In the treatment of excessive menstrual bleeding, Mirena causes a strong reduction in menstrual bleeding already within three months. Some users will have no periods at all.

When should Mirena be inserted?

Starting to use Mirena

- Before Mirena is inserted, it needs to be ensured that you are not pregnant.

- You should have Mirena inserted within 7 days from the start your menstrual period. When Mirena is inserted on these days, Mirena works right away and will prevent you getting pregnant.
- If you cannot have Mirena inserted within 7 days from the start of your menstrual period or if your menstrual period comes at unpredictable times, then Mirena can be inserted on any other day. In this case, you must not have had sexual intercourse without contraception since your last menstrual period, and you should have a pregnancy test before insertion. Also, Mirena may not reliably prevent pregnancy right away. Therefore, you should use a barrier method of contraception (such as condoms) or abstain from vaginal intercourse during the first 7 days after Mirena is inserted.
- Mirena is not suitable for use as an emergency contraceptive (postcoital contraceptive).

Starting to use Mirena after giving birth

- Mirena can be inserted after giving birth once the uterus has returned to normal size, but not earlier than 6 weeks after delivery (see section 2).
- See also “Starting to use Mirena” above for what else you need to know about the timing of insertion.

Starting to use Mirena after an abortion

Mirena can be inserted immediately after an abortion if the pregnancy was less than 3 months along provided that there are no genital infections. Mirena will then work right away.

Replacing Mirena

Mirena can be replaced by a new Mirena at any time of your menstrual cycle. Mirena will then work right away.

Changing from another contraceptive method (such as combined hormonal contraceptives or implant)

- Mirena can be inserted immediately if it is reasonably certain that you are not pregnant.
- If it has been more than 7 days since your menstrual bleeding began, you should abstain from vaginal intercourse or use additional contraceptive protection for the first 7 days after insertion.

When Mirena is used to protect the lining of the womb during estrogen replacement therapy, it can be inserted at any time in a woman who has no monthly bleeding, or during the last days of menstruation or withdrawal bleeding.

How is Mirena inserted?

Mirena should only be inserted by a healthcare professional who is experienced in Mirena insertions or has undergone sufficient training for Mirena insertion.

After a gynecological examination, an instrument called a speculum is inserted into the vagina, and the cervix is cleansed with an antiseptic solution. The IUS is then inserted into the womb via a thin, flexible plastic tube. Local anesthesia may be applied to the cervix to relieve pain, if necessary.

Some women may experience pain and dizziness after insertion. If these do not pass within half an hour in the resting position, the IUS may not be correctly positioned. An examination should be carried out and the IUS removed, if necessary.

After insertion of Mirena you should receive a patient reminder card from your doctor for follow-up examinations. Bring this with you to every scheduled appointment.

When should I see a doctor?

You should have your IUS checked 4–12 weeks after insertion, and thereafter regularly, at least once a year. Your doctor will determine how often and what kinds of check-ups are required in your particular case. Bring the patient reminder card you have received from your doctor to every scheduled appointment.

In addition, you should contact your doctor if any of the following occurs:

- You no longer feel the threads in your vagina with your fingers
- You can feel the lower end of the IUS with your fingers
- You think you may be pregnant
- You have persistent abdominal pain, fever, or unusual discharge from the vagina
- You or your partner feel pain or discomfort during sexual intercourse
- There are sudden changes in your menstrual periods (for example, if you first have little or no menstrual bleeding, and then you start having persistent bleeding or pain, or you start bleeding heavily)
- You have other medical problems, such as migraine headaches or intense headaches that recur, sudden problems with vision, jaundice, or high blood pressure
- You experience any of the conditions mentioned in section 2 "Before you use Mirena".

Tell healthcare professionals that you have Mirena inserted. Especially if they are not the person who inserted it.

For how long can Mirena be used?

Mirena is effective for 8 years when used for prevention of pregnancy (contraception). Are you using Mirena for this reason? If so, your Mirena should be removed or replaced after 8 years at the latest.

Mirena is effective for 5 years when used for heavy menstrual bleeding or for menstrual pain. Are you using Mirena for one of these reasons? If so, your Mirena should be removed or replaced when the heavy menstrual bleeding or menstrual pain returns or after 8 years at the latest.

Mirena is effective for 5 years when used as progestogen treatment during menopausal hormone replacement therapy. Are you using Mirena for this reason? If so, your Mirena should be removed or replaced after 5 years at the latest.

If you like, you may have a new Mirena inserted when the old one is removed.

What if I want to become pregnant or have Mirena removed for another reason?

The IUS can easily be removed at any time by your doctor, after which pregnancy is possible. Removal is usually a painless procedure. Fertility returns to normal after removal of Mirena.

Continuation of contraception after removal

If pregnancy is not desired, Mirena should not be removed after the seventh day of the menstrual cycle (monthly period) unless contraception is covered with other methods (e.g. condoms) for at least seven days before the removal. If you have irregular periods or no periods, you should use barrier methods of contraception for seven days before the removal of Mirena until your menstruation reappears. A new Mirena can also be inserted immediately after removal, in which case no additional protection is needed. If you do not wish to continue using the same method, ask your doctor for advice about other reliable contraceptive methods.

Can I become pregnant after stopping the use of Mirena?

Yes. After Mirena is removed, it does not interfere with your normal fertility. You may become pregnant during the first menstrual cycle after Mirena is removed.

Can Mirena affect my menstrual cycle?

Mirena does affect your menstrual cycle. It can change your menstrual periods in such a way that you have spotting (a small amount of blood loss), 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 Mirena inserted. Some women may have heavy or prolonged bleeding during this time. Please inform your doctor if this persists.

Overall, you are likely to have a gradual reduction in the number of bleeding days and in the amount of blood lost each month. Some women eventually find that periods stop altogether. As the amount of menstrual bleeding is gradually reduced during the use of Mirena, most women experience an increase in their blood hemoglobin value.

When the IUS is removed, periods return to normal.

Is it abnormal to have no periods?

Not when you are using Mirena. If you find that you do not have periods with Mirena, it is because of the effect of the hormone on the lining of the womb. The monthly thickening of the lining does no longer happen. Therefore, there is nothing to come away as a period. It does not necessarily mean that you have reached menopause or are pregnant. Your own hormone levels remain normal.

How will I know if I'm pregnant?

Pregnancy is unlikely in women using Mirena, even if they do not have periods.

If you have not had a period for six weeks and are concerned, then consider having a pregnancy test. If this is negative, there is no need to carry out another test unless you have other signs of pregnancy, e.g. nausea, tiredness or breast tenderness.

Can Mirena cause pain or discomfort?

Some women feel pain (like menstrual cramps) in the first few weeks after insertion. You should return to your doctor if you have severe pain or if the pain continues for more than three weeks after you have had Mirena inserted.

Will Mirena interfere with sexual intercourse?

Neither you nor your partner should feel the IUS during intercourse. If you do, intercourse should be avoided until your doctor has checked that the IUS is still in the correct position.

How long should I wait to have sexual intercourse after the insertion?

To give your body a rest, it is best to wait about 24 hours after having Mirena inserted before having sexual intercourse. Depending on when in your menstrual cycle Mirena is inserted, you might need to use a barrier contraceptive (such as condoms) or abstain from vaginal intercourse for the first 7 days after insertion (see section 3 "When should Mirena be inserted?").

Can I use tampons or a menstrual cup?

Use of sanitary pads is recommended. If you are using tampons or a menstrual cup, you should change them with care so as not to pull the threads of Mirena. If you think you may have pulled Mirena out of place (see "When should I see my doctor" for possible signs), avoid intercourse or use a barrier contraceptive (such as condoms), and contact your doctor.

What happens if Mirena comes out by itself?

It is rare but possible for Mirena to come out during your menstrual period without you noticing. An unusual increase in the amount of bleeding during your period could mean that Mirena has come out through your vagina. It is also possible for part of Mirena to come out of your womb (you and your partner may notice this during sexual intercourse). If Mirena comes out completely or partially, you will not be protected from pregnancy.

How can I tell whether Mirena is in place?

You can check yourself if the threads are in place. Gently put a finger into your vagina and feel for the threads at the end of your vagina near the opening of the womb.

Do not pull the threads because you may accidentally pull out Mirena. If you cannot feel the threads, this may indicate that the IUS has come out by itself or it has perforated the uterine wall. In this case you should use a barrier method (such as condoms) and contact your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

In addition to the possible side effects already mentioned in other sections (e.g. section 2 "What you need to know before you use Mirena"), here is a list of possible side effects by the parts of the body they affect and by how common they are:

Very common (in more than 1 out of 10 patients):

- Uterine/vaginal bleeding (including spotting), irregular periods (oligomenorrhea) and absence of bleeding (amenorrhea)
- Enlarged ovarian follicles (see Section 2 "Enlarged ovarian follicles_")

Common (in more than 1 out of 100 patients):

- Depressive mood / depression, nervousness, decreased libido
- Headache
- Dizziness
- Stomach pain, nausea
- Acne
- Back pain
- Pelvic pain, dysmenorrhea (painful menstruation), vaginal discharge, vulvovaginitis (infection of the external genital organs or vagina), breast tenderness, breast pain, expulsion of the IUS
- Weight increase

Uncommon (in less than 1 out of 100 patients):

- Migraine
- Abdominal distension
- Hair loss, hirsutism (excessive body hair), severe itching, eczema (skin infection), liver spots
- Pelvic inflammatory disease (upper genital tract infection, above the cervix), infection of the endometrium, infection of the cervix / Pap smear result normal, class II
- Edema (swelling)
- Perforation of the wall of the womb

Rare (in less than 1 out of 1,000 patients):

- Rash, urticaria (hives)

Cases of sepsis (very severe systemic infection, which may be fatal) have been reported following insertion of an intrauterine contraceptive.

If you become pregnant while using Mirena, there is a possibility that the pregnancy is outside the womb (see section 2 "Extrauterine pregnancy").

Cases of breast cancer have also been reported (frequency unknown).

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 (see the contact details below). By reporting side effects, you can help provide more information on the safety of this medicine.

website: www.fimea.fi

Finnish Medicines Agency Fimea

Lääkkeiden haittavaikutusrekisteri [*register of adverse drug reactions*]

PL 55

00034 FIMEA

5. How to store Mirena

Keep out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the package. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Mirena contains

- The active substance is levonorgestrel. One intrauterine delivery system contains 52 mg of levonorgestrel.
- The other ingredients are: hormone-elastomer core (polydimethylsiloxane and silica), T-body (polyethylene and barium sulfate), removal thread (polyethylene and iron oxide (E 172)).

What Mirena looks like and contents of the pack

Pack size: One sterile intrauterine delivery system

Marketing authorization holder and manufacturer

Bayer Oy
Pansiontie 47
20210 Turku

Marketed by

Bayer Oy
PL 73
02151 Espoo
Tel. 020 785 21

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Other sources of information

Detailed and up-to-date information on this medicine is available by using a smartphone to scan the QR code found on the package leaflet, the outer carton, and the patient reminder card. The same information is available at the Internet address www.mirena.fi or on the website of the Finnish Medicines Agency Fimea www.fimea.fi.

[QR code to package leaflet to be included nationally]