



Patient Information Leaflet

Patient Name: _____

Date of Fitting: _____

Doctor's Name: _____

Telephone No: _____

About this booklet

Please read this booklet carefully before you decide about using this method of contraception. It provides you with some useful information about Mirena®.

The information in this booklet applies only to Mirena®.

If you have any questions or are not sure about anything, please ask your doctor, nurse or clinic.

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.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT MIRENA IS AND WHAT IS IT 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 vertical arm of the white T-body carries a drug reservoir containing levonorgestrel. Two brown colored removal threads are tied to the loop at the lower end of the vertical arm.

Mirena is used for

- Contraception (prevention of pregnancy),

- Idiopathic menorrhagia (excessive menstrual bleeding)
- Protection from endometrial hyperplasia (excessive growth of the lining of the womb) during estrogen replacement therapy.

2. 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.

**About 2 in a 1000 women correctly using Mirena become pregnant in the first year.
About 7 in a 1000 women correctly using Mirena become pregnant in five years.**

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 take extra non-hormonal contraceptive precautions, e.g. use a condom 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 under any of the following conditions:

- if you are pregnant or think you might be pregnant
- if you currently or recurrently have a pelvic inflammatory disease (infection of the female reproduction organs)
- if you have a lower genital tract infection
- if you have an infection of the womb after delivery
- if you have had an infection of the womb after abortion during the past 3 months
- if you have an infection of the cervix (neck of the womb)
- if you have cell abnormalities in the cervix
- if you have cancer or suspected cancer of the cervix or womb
- if you have tumors which depend on progestogen hormones to grow,
- if you have unexplained abnormal uterine bleeding
- if you have abnormality of the cervix or womb including fibroids if they distort the cavity of the womb
- if you have conditions associated with increased susceptibility to infections
- if you have an active liver disease or liver tumor

- if you are hypersensitive (allergic) to levonorgestrel or to any of the other ingredients of Mirena.

Take special care with Mirena

Consult a specialist 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, asymmetrical visual loss 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.

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

You must see a doctor as soon as possible if you develop painful swelling in your leg, sudden chest pain or difficulty breathing as these may be signs of a blood clot. It is important that any blood clots are treated promptly.

It is advisable to give up smoking when using hormone-containing products such as Mirena.

In diabetic users of Mirena, the blood glucose concentration should be monitored. However, there is generally no need to change your diabetic treatment while using Mirena.

Irregular bleedings may mask some symptoms and signs of endometrial polyps or cancer, and in these cases diagnostic measures have to be considered.

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

Observational studies have not provided evidence of an increased risk of breast cancer during the use of Mirena. Due to confounding factors in Mirena trials in the indication, protection from endometrial hyperplasia (excessive growth of the lining of the womb) during estrogen replacement therapy, the available data is not sufficient to confirm or refute a risk for breast cancer when Mirena is used in this indication.

Medical examination/consultation

Examination before insertion may include a cervical smear test (Pap smear), examination of the breasts and other tests, e.g. for infections, including sexually transmitted diseases, as necessary. A gynecological examination should be performed to determine the position and size of the womb.

Mirena may not be suitable for use as postcoital contraceptive (used after intercourse).

Infections

The insertion tube helps to prevent 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 and during the first month after the insertion in Copper IUD users. Pelvic infections in IUS (Intra Uterine System) 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). 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.

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

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 or have heavy period. If the IUS is out of place, it may not work as intended. If the IUS is 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. As Mirena decreases menstrual flow, increase of menstrual flow may be indicative of an expulsion.

See “How can I tell whether Mirena is in place” for how to check if Mirena is in place and what to do if you suspect that Mirena is no longer in place.

Perforation

Perforation or penetration of the wall of the womb may occur, most often during placement, although it may not be detected until some time later. A Mirena which has become lodged outside the cavity of the womb is not effective in preventing pregnancy. You may need surgery to have Mirena removed. The risk of perforation is increased in breastfeeding women and in women who had a delivery up to 36 weeks before insertion and may be increased in women with the uterus fixed and leaning backwards (fixed retroverted uterus).

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 relatively increased. About 1 in a 1000 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 a 1000 women per year). Woman who already had an extrauterine pregnancy, surgery of the tubes from the ovaries to the womb or a pelvic

infection carry a higher risk. 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 contraceptive effect 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.

Additional information on special populations

Children and adolescents

Mirena is for use in women of childbearing age. There is no relevant indication for the use of Mirena before menarch (first menstrual bleeding).

Elderly patients (65 years or older)

Mirena has not been studied in women over the age of 65 years.

Patients with impaired liver function

Mirena must not be used in women with liver impairment (see under section 2, “Do not use Mirena”).

Patients with impaired kidney function

Mirena has not been studied in women with kidney impairment.

Taking other medicines

The mechanism of action of Mirena is mainly local, the intake of other medicines is not believed to increase the risk of pregnancy while using Mirena. However, it is advised that you tell your healthcare professional if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy

Mirena must not be used during an existing or suspected pregnancy.

It is very rare for a woman to become pregnant with Mirena in place. But 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 have Mirena removed as soon as possible. If Mirena is left in place during pregnancy, the risk of having a miscarriage, infection or preterm labor will be increased. If Mirena cannot be removed, talk with your healthcare provider about the benefits and risk of continuing the pregnancy, and possible effects of the hormone on the developing baby.

Breast-feeding

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 being transferred to the infant). 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 amount or the quality of breast milk.

Ask your doctor or pharmacist for advice before taking any medicine when you are pregnant or breast-feeding.

Driving and using machines

No known effects.

Important information about some of the ingredients of Mirena

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?

In contraception, Mirena is as effective as today's most effective copper IUDs. Mirena has a failure rate of 0.2% in the first year. The failure rate may increase in case of expulsion or perforation (see under section 2, "Medical examination/consultation").

In the treatment of idiopathic excessive menstrual bleeding Mirena causes a strong reduction of menstrual bleeding already after three months. Some users have no periods at all.

When should Mirena be inserted?

You can have Mirena inserted within seven days from the onset of the menstrual bleeding. The IUS can also be inserted immediately after a first trimester abortion provided that there are no genital infections. The IUS should be inserted only after the womb has returned to its normal size after delivery, and not earlier than 6 weeks after delivery (see section 2, “Before you use Mirena – Perforation”) . Mirena can be replaced by a new system at any time of the cycle.

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

Mirena should be inserted by a physician/health care professional who is experienced in Mirena insertion.

How is Mirena inserted?

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 (the inserter). Local anesthesia may be applied to the cervix prior to insertion, if appropriate.

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 may receive a patient reminder card from your doctor for follow-up examinations. Bring this with you to every scheduled appointment.

When should I see my doctor?

You should have your IUS checked 4 - 12 weeks after insertion, and thereafter regularly, at least once a year. If you received a patient reminder card from your doctor bring this with you 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
- You can feel the lower end of the system
- 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 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”.

For how long can Mirena be used?

Mirena is effective for five years if you are using it for contraception and idiopathic menorrhagia. The IUS has to be removed after five years.

If you are using it for protection from endometrial hyperplasia during oestrogen replacement therapy, clinical data beyond 4 years of use are limited. Mirena should therefore be removed after 4 years.

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

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 (menses) or no periods, you should use barrier methods of contraception for seven days before removal until your menstruation reappears. A new Mirena can also be inserted immediately after removal, in which case no additional protection is needed.

Can I become pregnant after stopping 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 periods?

Mirena does affect your menstrual cycle. It can change your menstrual periods so 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, especially 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 usually reduced with the use of Mirena, most women experience an increase in their blood hemoglobin value.

When the system 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 not 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.

In fact not having periods can be a great advantage for a woman's health.

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. sickness, 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 or clinic 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. However, as soon as it is inserted, Mirena will prevent pregnancy.

Can tampons or menstrual cups be used?

Use of sanitary pads is recommended. If tampons or menstrual cups are used, 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 your 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 after your period. Gently put a finger into your vagina after your period and feel for the threads at the end of your vagina near the opening of your womb (cervix).

Do not pull the threads because you may accidentally pull out Mirena. If you cannot feel the threads, this may indicate that an expulsion or perforation has occurred. In this case you should avoid intercourse or use a barrier contraceptive (such as condoms), and contact your doctor.

4. POSSIBLE SIDE EFFECTS

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

Below, we list possible side effects when Mirena is used for contraception (prevention of pregnancy) and idiopathic menorrhagia (excessive menstrual bleeding).

Possible side effects when Mirena is used for protection of endometrial hyperplasia (excessive growth of the lining of the womb) during estrogen replacement therapy were observed at a similar frequency unless specified by footnotes:

Very common: 10 or more in every 100 patients are likely to get these:

- Headache
- Abdominal/pelvic pain
- Bleeding changes including increased and decreased menstrual bleeding, spotting, oligomenorrhea (infrequent periods) and amenorrhea (absence of bleeding)
- Vulvovaginitis* (inflammation of the external genital organs or vagina)
- Genital discharge*

Common: between 1 and 10 in every 100 patients are likely to get these:

- Depressed mood/depression
- Migraine
- Nausea (feeling sick)
- Acne
- Hirsutism (excessive body hair)
- Back pain[§]
- Upper genital tract infection
- Ovarian cyst
- Dysmenorrhea (painful menstruation)
- Breast pain
- Intrauterine contraceptive device expelled (complete and partial)

Uncommon: between 1 and 10 in every 1,000 patients are likely to get these:

- Alopecia (hair loss)
- Uterine perforation

Unknown frequency:

- Hypersensitivity (allergic reaction) including rash, urticarial (hives) and angioedema (characterized by sudden swelling of e.g. the eyes, mouth, throat)
- Blood pressure increase

Description of selected possible side effects:

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

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 sepsis (very severe systemic infection, which may be fatal) have been reported following IUD insertion.

The following possible side effects have been reported in connection with Mirena insertion or removal procedures:

Procedural pain, procedural bleeding, insertion-related vasovagal reactions with dizziness or syncope (fainting). The procedure may result in a seizure (fit) in an epileptic patient.

The risk of breast cancer is unknown when Mirena is used in the indication protection from endometrial hyperplasia (excessive growth of the lining of the womb) during estrogen replacement therapy. Cases of breast cancer have been reported (frequency unknown).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

*Endometrial protection trials: "common"

§Endometrial protection trials: "very common"

5. HOW TO STORE MIRENA

Keep out of the reach and sight of children.

No special precautions for storage.

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

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Mirena contains

- The active substance is levonorgestrel 52 mg.
- The other ingredients are polydimethylsiloxane elastomer; silica, colloidal anhydrous; polyethylene; barium sulfate; iron oxide.

What Mirena looks like and contents of the pack

Pack size: One sterile intrauterine delivery system for intrauterine use

IF YOU HAVE ANY FURTHER QUESTIONS PLEASE CONSULT YOUR DOCTOR OR PHARMACIST.

Date of revision of the leaflet

09 Mar 2021

Manufacturer

Bayer Oy
Pansiontie 47 (P.O. Box 415)
20210 Turku Finland

Date of insertion = X Spotting = ○ Bleeding = ●

Month 1

1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

Month 2

1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

Month 3

1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

Month 4

1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				