

Patient Information Leaflet

Mirena® 20 micrograms/24 hours intrauterine delivery system (levonorgestrel)

About this leaflet

Please read this leaflet carefully before you decide to have Mirena fitted.

It provides you with some useful information about Mirena. The information in this leaflet applies only to Mirena. If you have any questions or are not sure about anything, please ask your doctor or nurse.

The name of your medicine is Mirena 20 micrograms/24 hours intrauterine delivery system but will be referred to as Mirena throughout the remainder of the leaflet.

In this leaflet:

1. What Mirena is and what it is used for
2. What you need to know before you use Mirena
3. How and when Mirena is used
4. Possible side effects
5. How to store Mirena
6. Further information

1. What Mirena is and what it is used for

Mirena is an intrauterine system (IUS) placed inside the womb (uterus) where it slowly releases the hormone levonorgestrel. It can be used in the following three ways:

1. As an effective long-term and reversible method of **contraception**. Mirena should be removed no later than 8 years after insertion when used for contraception.
2. For reducing menstrual blood flow, if you suffer from heavy periods (**heavy menstrual bleeding**). Mirena should be removed no later than 8 years after insertion when used for heavy menstrual bleeding. Inform your healthcare professional if your symptoms return.
3. If you are going through the menopause Mirena can be used in conjunction with an oestrogen as part of a **hormone replacement therapy (HRT) regimen** to protect the lining of your womb. Not so much is known about how well Mirena protects the lining of the womb beyond 4 years of use in women who are taking oestrogen to treat menopausal symptoms. Therefore, if you are using it in this way, your doctor or nurse will remove your Mirena no later than 4 years after insertion. Your doctor will be able to advise you further.

Children and adolescents

Mirena is not indicated for use before the first menstrual bleeding (menarche).

How does Mirena work?

As a **contraceptive**:

The hormone in Mirena prevents pregnancy by:

- controlling the monthly development of the womb lining so that it is not thick enough for you to become pregnant
- making the mucus in the opening to the womb (the cervical canal) thicker, so that the sperm cannot get through to fertilise the egg
- preventing the release of eggs (ovulation) in some women.

There are also some effects on the lining of the womb caused by the presence of the T-shaped frame of the Mirena device.

In the treatment of **heavy menstrual bleeding**: The hormone in Mirena reduces menstrual bleeding by controlling the monthly development of the womb lining, making it thinner, so that there is less bleeding every month.

As part of an **HRT regimen**:

The menopause is a gradual process which usually takes place between the ages of about 45 and 55. Although the menopause is natural, it often causes distressing symptoms such as hot flushes and night sweats. These symptoms are due to the gradual loss of the female sex hormones (oestrogen and progestogen) produced by the ovaries.

Oestrogens can be used to relieve the menopausal symptoms. However, taking oestrogens alone increases the risk of abnormal growth or cancer of the lining of the womb. Taking a progestogen, such as the hormone in Mirena (levonorgestrel), as part of an HRT regimen lowers this risk by protecting the lining of the womb.

2. What you need to know before you use Mirena

Your doctor or nurse will carry out some tests before you have Mirena fitted to make sure that it is suitable for you to use. This will include a pelvic examination so that pregnancy and sexually transmitted diseases can be excluded and may also include other examinations such as a breast examination, if your doctor or nurse feels this is appropriate.

Genital infections will need to be successfully treated before you can have Mirena fitted.

Mirena is not suitable for use as an emergency contraceptive (postcoital contraceptive).

If Mirena is to be fitted for HRT use your doctor will firstly carry out an assessment of your symptoms to ensure that treatment is only initiated for symptoms that adversely affect your quality of life. Such an assessment should be repeated by your doctor at least annually. You should also consult the Patient Information Leaflet of the oestrogen product that is to be used in conjunction with Mirena before starting your HRT regimen as there are some important risk factors associated with HRT that you should consider, such as the risk of endometrial cancer, breast cancer and blood clots.

If you have epilepsy, tell the doctor or nurse fitting the Mirena because, although rare, a fit can occur during insertion or removal.

You may feel pain or have some bleeding during insertion. Some women might feel faint after the procedure. This is normal and your doctor or nurse will tell you to rest for a while.

Do not use Mirena and please tell your doctor or nurse if you:

- are pregnant or suspect that you may be pregnant
- have or have had any type of cancer or suspected cancer including blood cancer (leukaemia) unless in remission, uterine, cervical and breast cancer
- currently have or have had recurrent pelvic inflammatory disease
- have or have had inflammation of the neck of the womb (cervix)
- have an unusual or unpleasant vaginal discharge, or vaginal itching as this may indicate an infection
- have or have had inflammation of the lining of your womb following delivery of your baby
- have or have had an infection of the womb after delivery or after abortion during the past 3 months
- have any condition which makes you susceptible to infections. A doctor will have told you if you have this
- have or have had an abnormal smear test (changes in the cervix)
- have undiagnosed vaginal bleeding
- have an abnormal womb or abnormal growths in the womb (fibroids) which distort the uterine cavity
- have or have had liver problems
- have or have had trophoblastic disease. A doctor will have told you if you have this
- are sensitive to the hormone levonorgestrel or to any of the ingredients in Mirena (see section 6 'What Mirena contains').

Mirena must not be used as part of an HRT regimen if you have had a stroke, heart attack or any heart problems.

Warnings and precautions

Mirena may not be suitable for all women.

Consult your doctor or nurse if you:

- have or develop migraine with visual disturbances, unusually bad headaches or if you have headaches more often than before
- have yellowing of the skin or whites of the eyes (jaundice)
- have high blood pressure
- have had a cancer affecting your blood (including leukaemia) which is now in remission
- are on long-term steroid therapy
- have ever had a previous ectopic pregnancy (pregnancy outside the womb)
- have a history of fluid filled sacks in the ovary (ovarian cysts)
- are having Mirena fitted for contraception or heavy menstrual bleeding and have had a stroke or heart attack, or if you have any heart problems
- disease of your arteries (arterial disease)
- have a history of blood clots (thrombosis)
- are diabetic, as Mirena may affect glucose tolerance.

You may still be able to use Mirena if you have or have had some of these conditions. Your doctor or nurse will advise you.

You must also tell your doctor or nurse if any of these conditions occur for the first time while you have Mirena in place.

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.

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

You must also **see a doctor without delay if you develop persistent lower abdominal pain, fever, pain during sexual intercourse or abnormal bleeding**. If you get severe pain or fever shortly after Mirena has been inserted, you may have a severe infection which **must** be treated immediately.

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

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 section 3 'How and when Mirena is used – How can I tell whether Mirena is in place?'), avoid intercourse or use a barrier contraceptive (such as condoms), and contact your doctor.

Can I change my mind?

Your doctor or nurse can remove Mirena at any time. Unless you wish to get pregnant the removal should be carried out during the first 7 days of your period. Otherwise it is important to use another form of contraception (e.g. condoms) in the 7 days leading up to the removal as intercourse during this week could lead to pregnancy after Mirena is removed.

If you do wish Mirena to be removed so that you can get pregnant your usual level of fertility is expected to return after it is removed. Studies have suggested that in women who discontinue Mirena (in order to become pregnant) the pregnancy rate at one year is similar to those who do not use contraception.

Taking other medicines

The effect of hormonal contraceptives such as Mirena may be reduced by medicines that increase the amounts of enzymes made by the liver. Please tell your doctor or nurse if you are taking any:

- medicines used to treat epilepsy
- antifungal medicines (e.g. griseofulvin, fluconazole, itraconazole, ketoconazole, voriconazole)
- certain antibiotics (rifampicin & macrolides (e.g. clarithromycin, erythromycin))
- medicines used to treat HIV and Hepatitis C Virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors)
- certain sedatives (called barbiturates)
- medicines used to treat chest pain (angina) and/or high blood pressure
- products containing St John's Wort (a herbal remedy).

Please tell your doctor or nurse if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

Pregnancy and breastfeeding

Mirena should not be used during pregnancy or if you think you are pregnant.

It is very rare for women to become pregnant with Mirena in place.

Missing a period may not mean that you are pregnant as some women may not have periods at all while using Mirena. However, in order to exclude the possibility of pregnancy, you should consider a pregnancy test if you have not had a period for 6 weeks. If this test 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.

If you become pregnant with Mirena in place, you should see 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 labour. If Mirena cannot be removed, ectopic pregnancy should be excluded and 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 pregnancy and you should contact your doctor right away 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 intra-uterine devices while in the womb.

Very small amounts of the hormone in Mirena are found in breast milk but the levels are lower than with any other hormonal contraceptive method. Please ask your doctor or nurse for advice before breastfeeding.

3. How and when Mirena is used

Placement of Mirena:

Mirena should be inserted by a healthcare professional who is experienced in Mirena insertion. They will explain the fitting procedure and any risks associated with its usage. You will then be examined by your doctor or nurse before Mirena is fitted. If you have any concerns over its usage you should discuss it with them.

For contraception or heavy menstrual bleeding:

Starting to use Mirena:

- Before Mirena is inserted, it needs to be ensured you are not pregnant.
- You should have Mirena inserted within 7 days from the start of your period. When Mirena is inserted on these days, Mirena works right away and will prevent you getting pregnant.
- If you cannot have Mirena inserted 7 days from the start of your period or if your 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 period, and you should have a negative pregnancy test. 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).
- The possibility of becoming pregnant is approximately 2 in 1,000 in the first year. The failure rate may increase in case of Mirena coming out by itself (see below section 'What happens if Mirena comes out by itself?') or perforation (see section 4 'Possible side effects').
- Mirena usually results in lighter periods after 3 to 6 months of treatment.

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 4 'Possible side effects – Severe pain and continued bleeding').
- 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 with 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 contraceptive, 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 next 7 days.

For HRT use:

- If you no longer have periods then Mirena can be inserted at any time. If you still have periods, Mirena should be inserted during the last days of bleeding. Remind your healthcare provider that you have Mirena inserted, especially if they were not the person who inserted it.
- The hormone in Mirena will begin to protect the lining of your womb as soon as it is fitted.

How often should I have Mirena checked?

You should have it checked 6 weeks after it is fitted. Your doctor may determine how often and what kind of check-ups are required in your particular case. If you received a patient reminder card from your doctor bring this with you to every scheduled appointment.

How can I tell whether Mirena is in place?

Gently put a finger into your vagina and feel for the two thin threads attached to the lower end of Mirena. Your doctor or nurse will show you how to do this.

Mirena is a registered trademark of Bayer Oy

Date of preparation 6th November 2025

Blind or partially sighted? Is this leaflet hard to see or read? Contact Quadrant Pharmaceuticals Ltd, Tel: 01204 471269

Other sources of information

Detailed and updated information on this medicine is available by scanning the QR Code included in the package leaflet, outer carton and patient reminder card with a smartphone. The same information is also available on the following URL: www.pi.bayer.com/mirena/uk and on the website of the MHRA (<https://www.gov.uk/pil-ipc>).



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				

- skin discolouration/increased skin pigment especially on the face (chloasma)

Rare (less than 1 in 1000 women)

- rashes

Unknown frequency

- allergic reaction (symptoms may include rash, itching or rapid swelling of the face, mouth, tongue and/or throat)
- increased blood pressure

Your partner may feel the removal threads during intercourse.

Every woman is at risk of breast cancer, but it is rare in women under the age of 40. Breast cancer has been reported in Mirena users, although the risk and frequency are unknown.

In pre-menopausal women, the frequency of developing breast cancer whilst using Mirena is possibly similar to that associated with using Combined Oral Contraceptives, but the evidence for this is less conclusive.

In post-menopausal women, using hormone replacement therapy (HRT) slightly increases the risk of breast cancer. Although the risk of developing breast cancer is higher with combined oestrogen/progestogen HRT, than with oestrogen-only HRT, the risk of breast cancer developing when Mirena is prescribed to provide the progestogen component of HRT is not yet known. The patient information leaflet of the oestrogen component of the treatment should also be consulted for additional information.

It is important to regularly check your breasts and you should contact your doctor if you feel any lump in your breasts. You should also tell your doctor if a close relative has or ever had breast cancer.

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 nurse.

Reporting of side effects

If you get any side effects talk to your doctor, pharmacist, nurse or other healthcare professional. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: <https://yellowcard.mhra.gov.uk> or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine. For long-acting products like Mirena, please report information of when Mirena was inserted and removed, as applicable.

5. How to store Mirena

Keep out of the sight and reach of children.

Do not use this medicine after expiry date stated on the label and carton after EXP. The expiry date refers to the last day of that month. No special storage conditions.

If your medicine shows any signs of deterioration or discolouration, consult your doctor or pharmacist for advice. If damaged, please tell your doctor or pharmacist.

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

6. Further Information

What Mirena contains

The active ingredient is levonorgestrel. Mirena contains 52 milligrams of levonorgestrel. The hormone is contained within a substance called polydimethylsiloxane. This is surrounded by a membrane (skin) also made of polydimethylsiloxane (which contains silica, colloidal anhydrous). The Mirena T-shaped frame also contains barium sulphate so that it can be seen on X-rays.

What Mirena looks like and contents of the pack

Mirena consists of a small white T-shaped frame made from a plastic called polyethylene. There are two fine brown threads, made of iron oxide and polyethylene, attached to the bottom of the frame. These allow easy removal and allow you or your doctor or nurse to check that Mirena is in place.

Each sterile pack contains one Mirena and should not be opened until required.

Manufactured by: BAYER OY, PANSIONTIE 47, 20210 TURKU, FINLAND. Procured from within the EU. Product Licence Holder: Quadrant Pharmaceuticals Limited, Lynstock House, Lynstock Way, Lostock, Bolton, BL6 4SA. Repackaged by: Maxearn Limited, Unit 29, Oakhill Trading Estate, Devonshire Road, Worsley, Manchester, M28 3PT.

If you have had Mirena fitted for **heavy menstrual bleeding**:

You should have lighter periods after 3 to 6 months. If you do not have lighter periods after 3 to 6 months, alternative treatments should be considered.

If you have had Mirena fitted for **HRT use**:

If you develop any new vaginal bleeding or experience a change in bleeding patterns after using Mirena for some time, consult your doctor or nurse as this could be a sign that Mirena has been expelled, is not working well enough for you or there are changes to your womb.

4. Possible side effects

Taking any medicine carries some risk of side effects. With Mirena these are most common during the first months after it is fitted and decrease as time goes on.

If you experience any of the following serious side effects please contact your doctor or nurse immediately:

- **Severe pain or fever developing shortly after insertion** may mean that you have a severe infection which **must** be treated immediately. In rare cases very severe infection (sepsis) can occur.
- **Severe pain and continued bleeding** as this might be a sign of damage or tear in the wall of the womb (perforation). Perforation is uncommon, but occurs most often during placement, although it may not be detected until sometime later. A Mirena which has become lodged outside the cavity of the womb is not effective in preventing pregnancy and must be removed as soon as possible. You may need to have 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). If you suspect you may have experienced a perforation, seek prompt advice from a healthcare provider and remind them that you have Mirena inserted, especially if they were not the person who inserted it.

Possible signs and symptoms of perforation may include:

- ▷ severe pain (like menstrual cramps) or more pain 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 Mirena threads (see section 3 'How and when Mirena is used – How can I tell whether Mirena is in place?').

- **Lower abdominal pain especially if you also have a fever or have missed a period or have unexpected bleeding**, as this might be a sign of ectopic pregnancy. The absolute risk of ectopic pregnancy in Mirena users is low. However, when a woman becomes pregnant with Mirena in place, the relative likelihood of ectopic pregnancy is increased.
- **Lower abdominal pain or experience painful or difficult sex** as this might be a sign of ovarian cysts or pelvic inflammatory disease. This is important as pelvic infections can reduce your chances of having a baby and can increase the risk of ectopic pregnancy.

Very Common (more than 1 in 10 women)

- vaginal bleeding including spotting
- absent, light or infrequent menstrual periods

Common (less than 1 in 10 women)

- ovarian cysts
- painful periods
- weight gain
- depression, nervousness
- headache
- migraine
- dizziness
- abdominal, pelvic or back pain
- nausea
- acne
- increased growth of hair on the face and body
- reduced sex drive
- increased vaginal discharge
- inflammation of the vulva and vagina
- tender, painful breasts
- Mirena coming out by itself

Uncommon (less than 1 in 100 women)

- uterine perforation (see 'serious side effects' above)
- genital infections that may cause: vaginal itching; pain on passing urine; or lower abdominal pain from inflammation of the womb, ovaries or Fallopian tubes
- infection or inflammation of the lining of the womb, which may cause a foul smelling vaginal discharge (endometritis)
- inflammation of the neck of the womb (cervicitis)
- swelling of your abdomen, legs or ankles
- hair loss
- itchy skin including eczema

Do not pull the threads because you may accidentally pull it out. If you cannot feel the threads, contact your doctor or nurse as soon as possible and in the meantime avoid intercourse or use a barrier contraceptive (such as condoms). The threads may have simply drawn up into the womb or cervical canal. If the threads still cannot be found by your doctor or nurse, they may have broken off, or Mirena may have come out by itself, or in rare cases it may have perforated the wall of your womb (uterine perforation, see section 4). It may be necessary for you to have an ultrasound scan or x-ray to locate Mirena.

Contact your doctor or nurse if you can feel the lower end of Mirena itself or you or your partner feel pain or discomfort during sexual intercourse.

What happens if Mirena comes out by itself?

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 IUS insertion or have a history of heavy periods. If the IUS is out of place, it may not work as intended and therefore, the risk of pregnancy is increased. 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.

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

Removal of Mirena:

Some women feel dizzy or faint during or after Mirena is removed. You may experience some pain and bleeding during removal of Mirena.

Contraception:

Mirena should be removed no later than 8 years after insertion when used for contraception.

Mirena can be easily removed at any time by your healthcare professional, after which pregnancy is possible. Unless you plan to have a new system or an intra-uterine device fitted immediately, it is important to use another form of contraception (e.g. condoms) for at least 7 days leading up to the removal. Intercourse during this week could lead to pregnancy after Mirena is removed. If you do not wish to continue using the same method, ask your doctor for advice about other reliable contraceptive methods.

Heavy menstrual bleeding:

Mirena should be removed no later than 8 years after insertion when used for heavy menstrual bleeding. Inform your healthcare professional if your symptoms return, Mirena will then be removed or replaced.

Using Mirena as part of an HRT regimen:

Mirena should be removed no later than 4 years after insertion when you are using Mirena as part of an HRT regimen.

How will Mirena affect my periods?

Mirena will affect your menstrual cycle.

For **all uses** of Mirena:

You may have lighter periods or painful periods or some spotting (light bleeding in between periods) and irregular bleeding during the first few months after Mirena is fitted.

You may have prolonged or heavy bleeding or an increase in the frequency of bleeding, usually in the first 2 to 3 months, before a reduction in blood loss is achieved.

Overall you are likely to have fewer days bleeding in each month and you might eventually have no periods at all. This is due to the effect of the hormone (levonorgestrel) on the lining of the womb.

If you develop any new vaginal bleeding or experience a change in bleeding patterns after using Mirena for some time, consult your doctor or nurse as this could be a sign that Mirena has been expelled or is not working well enough for you.

There is a calendar at the end of this patient information leaflet. Your doctor or nurse may ask you to fill this in to check your pattern of bleeding. If you are asked to do so, mark the date of insertion with an "X" in the appropriate date square. Mark days of spotting with "○" and bleeding with "●".