

PACKAGE LEAFLET: INFORMATION FOR THE USER

MIRENA

20micrograms/24 hours intrateurine delivery system

LEVONORGESTREL

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking 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 •

What is in this leaflet?

1. What MIRENA is and what it is used for
2. Before you take MIRENA
3. How to take MIRENA
4. Possible side effects
5. Further information

1. WHAT MIRENA IS AND WHAT IS IT 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**.
2. For reducing menstrual blood flow, if you suffer from heavy periods (**heavy menstrual bleeding**).

It can be used for contraception and heavy menstrual bleeding until it is removed or up to a maximum of 5 years.

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 after 4 years. Your doctor will be able to advise you further.

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. BEFORE YOU TAKE 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.

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. You may feel pain or have some bleeding during insertion.

If you have epilepsy, tell the doctor or nurse fitting the Mirena because, although rare, a fit can occur 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 5 '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.

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.

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.

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 few 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:

- phenobarbital, primidone, phenytoin or carbamazepine (to treat epilepsy)
- griseofulvin (an antifungal)
- rifampicin or rifabutin (antibiotics)
- nevirapine or efavirenz (for HIV).

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 do become pregnant with Mirena in place, please contact your doctor as soon as possible so that ectopic pregnancy can be excluded and Mirena removed to reduce the risk of spontaneous abortion.

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 TO TAKE MIRENA

Only a doctor or specially trained nurse can fit Mirena. 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.

When Mirena is fitted for **contraception** or **heavy menstrual bleeding**: Mirena should be inserted either during your period or within seven days from the beginning of your period. If you already have Mirena and it is time to

replace it with a new one, you do not need to wait until your period. If you have just had a baby, you should wait at least 6 weeks before having Mirena fitted (see section 4 “Possible side effects – Severe pain and continued bleeding”). Mirena can sometimes be fitted immediately after you have had an abortion, provided that you have no genital infections.

When Mirena is fitted 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.

How quickly does Mirena work?

Contraception:

You are protected from pregnancy as soon as Mirena is fitted. The possibility of becoming pregnant is approximately 2 in 1,000 in the first year. The failure rate may increase in case of the Mirena coming out by itself (see page XX) or perforation (see page XX ‘Side Effects’).

Heavy menstrual bleeding:

Mirena usually results in lighter periods after 3 to 6 months of treatment.

HRT use:

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.

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.

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?

If it comes out either completely or partially you may not be protected against pregnancy.

It is rare but possible for this to happen without you noticing during your menstrual period. An unusual increase in the amount of bleeding during your period might be a sign that this has happened. Tell your doctor or nurse if there are any unexpected changes in your bleeding pattern.

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 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 have had Mirena fitted for quite a long time and then start to have bleeding problems, **it is important that you contact your doctor** so that tests can be carried out to exclude 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 rare, but occurs most often during the fitting of the Mirena, although the perforation may not be detected until sometime later. If this happens the Mirena will be removed; very rarely this may require surgery. The risk of perforation is low, but is increased in breastfeeding women and in women who have had a baby up to 36 weeks before insertion.

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
- 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)

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

Rare (less than 1 in 1000 women)

- rashes
- uterine perforation (see 'serious side effects' above)

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 booklet, please tell your doctor or nurse.

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

5. FURTHER INFORMATION

What Mirena contains

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.

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 T-shaped frame made from a plastic called polyethylene. There are two fine 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.

Product Licence Holder:

Bayer plc, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA

Mirena is manufactured by:

Bayer Oy, Pansiontie 47, 20210 Turku, Finland