

MIRENA[®] (Mi-RAY-na)

levonorgestrel intrauterine delivery system

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Mirena. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Mirena against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

WHAT MIRENA IS USED FOR

Mirena consists of a small T-shaped frame made from a plastic called polyethylene. This carries 52 mg levonorgestrel, a hormone used in many contraceptive pills. The hormone is contained within a substance called dimethylsiloxane/methylvinylsiloxane cross linked elastomer and is surrounded by a membrane (skin) also made of the same elastomer.

This structure provides a system for releasing the hormone gradually into the womb (uterus).

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 to check that the system is in place.

Mirena may be used as a long term and reversible method of contraception, for the treatment of excessive menstrual bleeding (menorrhagia) or for protection from endometrial hyperplasia (excessive growth of the lining of the womb) during hormone replacement therapy. It is placed inside the womb where it slowly releases the hormone (at an initial rate of 20 micrograms per 24 hours) over a period of five years or until it is removed.

Mirena works in the treatment of excessive monthly bleeding and as protection in estrogen replacement therapy by slowly releasing the progestogen hormone levonorgestrel, within the womb. Levonorgestrel suppresses the response of the cells in the lining of the womb to estrogen making the lining of the womb insensitive to circulating oestradiol. This stops the growth of the lining of the womb, which results in a reduction in the volume and duration of menstrual bleeding. This is the mechanism of action in the treatment of excessive bleeding (menorrhagia) and for protection against over stimulation of the lining of the womb in estrogen replacement therapy.

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 normal mucus in the cervical canal (opening to the womb) thicker, so that the sperm cannot get through to fertilise the egg
- preventing ovulation (the release of eggs) in some women
- there are also local effects on the lining of the womb caused by the presence of the T-shaped frame - since Mirena is an intrauterine system (IUS)
- affecting the movement of sperm inside the womb, preventing fertilisation.

Mirena is not an emergency contraceptive.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

BEFORE YOU USE MIRENA

Not all women can use Mirena. All products have benefits and risks. If you are unsure if Mirena is suitable for you, discuss this with your doctor.

Mirena should not be the first choice of contraception in

young women who have not had a baby.

When you must not use it

Do not use Mirena if you have an allergy to:

- levonorgestrel, the active ingredient in Mirena
- any of the inactive ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty in breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not use this medicine if you are pregnant or suspect you may be pregnant.

Do not give it to a child.

Do not use Mirena if you have, or have had any of the following medical conditions:

- undiagnosed vaginal bleeding from the womb
- abnormal cervix or womb, or fibroids which distort the cavity of the womb
- progestogen dependent tumours
- tumours in the cervix or womb
- liver disease or liver tumour
- if you have pelvic inflammatory disease or have had recurrent pelvic inflammatory disease in the past (infection of the female reproductive organs)
- if you have conditions associated with increased risk of developing pelvic infections
- lower genital tract infections

- infections of the womb after childbirth or after an abortion in the last three months
- infection or cell abnormalities in the cervix (opening to the womb)

Do not use this medicine after the expiry date printed on the pack.

If it has expired or is damaged, return it to your pharmacist for disposal. The expiry date is printed on the carton and on the sachet after “To be inserted before” (e.g. 11 18 refers to November 2018). The expiry date refers to the last day of that month by which it should be inserted.

Do not use this medicine if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Before insertion, your doctor will inform you of the benefits and risks of Mirena. A physical examination including pelvic examination, examination of the breasts and a Pap smear should be performed.

Your doctor should also rule out pregnancy. Any sexually transmitted infections (STIs) and genital infections should be treated successfully before insertion.

Your doctor will also need to do a gynaecological examination to

determine the position and the size of your womb.

Your doctor may consider removal of the system if any of the following conditions exist or arise for the first time.

Mirena should be used with caution after specialist consultation.

- migraine with visual disturbances or other symptoms which may be signs of a temporary blockage of blood supply to the brain
- severe headaches
- jaundice (yellowing of the skin and eyes)
- increase in blood pressure
- stroke or heart attack
- blood clots in the legs (deep vein thrombosis), the lungs (pulmonary embolism) or other parts of the body.

Tell your doctor if you have any of the following conditions, Mirena may be used with caution:

- if you were born with heart disease (congenital) or valvular heart disease
- diabetes, there is generally no need to alter your diabetic medication while using Mirena but this may need to be checked by your doctor

Pelvic infections have been reported with the use of intrauterine delivery systems such as Mirena. You have an increased risk of pelvic infections if you have multiple sexual partners, STIs or a history of pelvic inflammatory disease. Pelvic infections may impair fertility and increase the risk of ectopic pregnancy.

Pain, bleeding or dizziness may occur when Mirena is placed or

removed. **If you have epilepsy, tell your doctor because seizures can occur during placement or removal.**

If you have not told your doctor about any of the above, tell them before you start using Mirena.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Mirena may interfere with each other. These include:

- medicines to treat high blood pressure, chest pain and/or irregular heartbeats such as verapamil, diltiazem
- medicines used to treat epilepsy such as phenytoin, barbituates, primidone, carbamazepine, felbamate, topiramate, oxcarbazepine
- rifampicin or rifabutin for the treatment of tuberculosis
- macrolide antibiotics (e.g. clarithromycin, erythromycin)
- herbal medicines containing St John's Wort
- medicines used to treat HIV/AIDS such as efavirenz or nevirapine
- some medicines used to treat Hepatitis C Virus (HCV) such as boceprevir, telaprevir
- medicines used to treat fungal infections such as ketoconazole, itraconazole, voriconazole, fluconazole, griseofulvin
- grapefruit juice

These medicines may be affected by Mirena or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

HOW TO USE MIRENA

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions given, ask your doctor or pharmacist for help.

How to use it

Mirena is inserted and removed by a professional, experienced in the use of IUSs.

When to use it

The system should be inserted within seven days from the beginning of your period. If you already have the system and it is time to replace it with a new one, you do not need to wait for your period.

Mirena can be inserted immediately after a first trimester abortion. It should not be used until the womb has returned to normal size after giving birth and no earlier than six weeks after delivery.

When Mirena is used to protect the lining of the womb during

estrogen replacement therapy, it can be inserted at any time if you do not have monthly bleeding or else during the last days of menstruation or withdrawal bleeding. You may feel faint after the system is inserted. This is normal and your doctor will tell you to rest for a while.

WHILE USING MIRENA

The current recommendation is to wait about 24 hours after having Mirena inserted before having sexual intercourse.

You may feel faint after Mirena is placed. This is normal and your doctor will tell you to rest for a while. In rare cases, part or all of the system could penetrate the wall of the womb. If this happens, Mirena needs to be removed.

You should have Mirena checked usually 4-12 weeks after it is placed and then once a year until it is removed. It can stay in place for five years.

Your doctor can remove the system at any time and removal is usually easy. Mirena should be removed before the seventh day of the menstrual cycle unless another form of contraception is used in the week leading up to the removal. Intercourse during this week could lead to pregnancy after Mirena is removed.

Mirena does not protect against HIV infection (AIDS) and other STIs. Additional methods should be used (i.e. condoms) to prevent transmission of STIs.

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

Expulsion

If the system comes out either partially or completely you may not be protected against pregnancy. It is rare but possible for this to happen without you noticing during your menstrual period. The muscular contractions of the womb during menstruation may sometimes push the IUS out of place or expel it. Possible symptoms are pain and increased amount of bleeding.

If you have signs indicative of an expulsion or you cannot feel the threads you should either avoid intercourse or use another contraceptive (e.g. condoms) and consult your doctor.

After each menstrual period, you can feel for the two thin threads attached to the lower end of the system. Your doctor will show you how to do this. Do not pull on the threads because you may accidentally pull it out. If you cannot feel the threads, consult your doctor.

You should see your doctor if you can feel the lower end of the system itself or you or your partner feel pain or discomfort during sexual intercourse.

If Mirena is expelled, telephone Bayer Drug Safety (telephone: 1800 673 270 in Australia, or 0800 229 376 in New Zealand) for advice on how to dispose of Mirena.

Bleeding patterns

Many women have frequent spotting or light bleeding in

addition to their periods for the first 3-6 months after they have had Mirena inserted. Overall, you are likely to have a gradual reduction in the number of bleeding days and in the amount of blood loss. Some women eventually find that their periods stop altogether.

If you are using Mirena with estrogen replacement therapy, a non-bleeding pattern is likely to develop during the first year of use.

Tell your doctor if bleeding remains heavy or irregular.

Perforation

Mirena can perforate the wall of the womb (most often during placement). The risk of perforation increases in breastfeeding women and in postpartum (after giving birth) insertions. The risk may also be increased in women with a fixed retroverted uterus (tilted womb). If this happens, the IUS must be removed as soon as possible. **If you experience excessive pain or bleeding after insertion, tell your doctor immediately.**

Ectopic pregnancy

It is very rare to become pregnant while using Mirena. However, if you become pregnant while using Mirena, the risk of an ectopic pregnancy (where the foetus is carried outside of your womb) is increased

The risk of an ectopic pregnancy happening is lower than for women using no contraception.

Although the rate of pregnancy is low, if you suspect you are pregnant, you

should see your doctor straight away.

Ectopic pregnancy can cause internal bleeding, infertility, and death. **It is a serious condition that requires immediate medical attention.**

The following symptoms could mean that you may have an ectopic pregnancy and you should see your doctor immediately:

- your menstrual periods cease 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

There are also risks if you get pregnant while using Mirena and the pregnancy is in the womb. Miscarriage and premature delivery can occur with pregnancies that continue with an intrauterine device or system (IUD/IUS). Because of this, your doctor may try to remove Mirena, even though removing it may cause a miscarriage. If Mirena cannot be removed, talk with your healthcare provider about the benefits and risks of continuing the pregnancy.

If you continue your pregnancy, see your doctor regularly. Call your doctor right away if you get flu-like symptoms, fever, chills, cramping, pain, bleeding, vaginal discharge, or fluid leaking from your vagina. These may be signs of infection. It is not known if Mirena can cause long-term effects on the

foetus if it stays in place during a pregnancy.

Pelvic infections

The Mirena system and insertion technique have been designed to minimise the risk of infections. Despite this, there is an increased risk of pelvic infection immediately and during the first month after insertion. Pelvic infections can occur with contamination of the IUS. You have an increased risk of pelvic infections if you have multiple sexual partners, STIs or a history of pelvic inflammatory disease. When having sex with anybody who is not a long-term partner, a condom should be used to minimise the risk of infection with HIV, hepatitis B and other STIs.

Pelvic infections must be treated promptly. Pelvic infection may impair fertility and increase the risk of ectopic pregnancy.

Mirena must be removed if there are recurrent pelvic infections or if an infection does not respond to treatment within a few days. Tell your doctor immediately if you have persistent lower abdominal pain, fever, pain during sexual intercourse or abnormal bleeding.

As with other gynaecological or surgical procedures, severe infections or sepsis can occur following IUD insertions.

Ovarian Cysts

Ovarian cysts or enlarged group of cells (follicles) have been reported with the use of Mirena and may cause pelvic pain or pain during intercourse. You

may not experience any symptoms with ovarian cysts or follicles. In most cases, the follicles resolved spontaneously. Your doctor will monitor you while you are using Mirena. Keep all of your doctor's appointments.

Breast cancer

Breast cancer has been detected slightly more often in women who use combined oral contraceptives (the Pill) compared to women of the same age who do not use the Pill. It is not known whether the difference is caused by the Pill or whether cancers were detected earlier in Pill users. The evidence is not conclusive for progestogen-only presentations such as Mirena. Available data is not conclusive for whether Mirena increases your risk for breast cancer when using Mirena during estrogen replacement therapy. The patient information leaflet of the estrogen replacement therapy should also be consulted for additional information. Should breast cancer be diagnosed, your doctor may consider removal of Mirena.

If you are breastfeeding

There is a small amount of the progestogen hormone levonorgestrel, which will be absorbed by babies who are breastfeeding when Mirena is used. This is an equivalent amount to that received by babies when the mother is using the minipill (a progestogen only contraceptive). There has been extensive experience with the minipill during breastfeeding, indicating no harmful effects to breastfed babies.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Mirena.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

During placement or removal of Mirena, the following side effects have been reported: pain, bleeding, dizziness and fainting.

Side effects are most common during the first months after the system is placed and decrease as time goes on. It is normal to experience changes in menstrual patterns during the use of Mirena. The changes may include spotting, shorter or longer menstrual periods, irregular bleeding, prolonged periods of no bleeding at all, heavy flow and menstrual pain.

Tell your doctor or pharmacist if you notice any of the following, particularly if they worry you:

- nervousness
- depressed mood, mood swings
- lower abdominal/pelvic pain or back pain
- bleeding changes including increased or decreased menstrual bleeding,

- spotting, infrequent or light periods, absence of bleeding
- headache, migraine
- nausea
- acne
- excessive hairiness
- tender or painful breasts
- period pain
- itching, redness and/or swelling of the vagina
- vaginal discharge
- weight gain
- decreased libido
- expulsion of Mirena

The above list includes the common side effects of your medicine.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- signs of allergy such as rash, swelling of the face, lips, mouth, throat or other parts of the body, shortness of breath, wheezing or trouble breathing
- excessive abdominal pain or vaginal bleeding
- fever, chills or generally feeling unwell

You may need urgent medical attention or hospitalisation if you experience the above side effects.

Cases of allergic reactions such as rash, hives and swelling have been reported with the use of Mirena.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

STORAGE

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Store Mirena in a cool dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a window-sill.

Do not leave it in the car. Heat and dampness can destroy some medicines.

PRODUCT DESCRIPTION

What it looks like

Mirena is a small, white coloured T-shaped plastic system. Two brown removal threads are attached to the lower end of the vertical arm.

The T-shaped frame also contains barium sulfate so that it can be seen on X-rays.

Mirena is contained within an insertion device and is provided in a sterile pouch for insertion by a doctor experienced in the insertion of IUSs.

Ingredients

Active ingredient:

- Mirena – 52 mg of levonorgestrel per IUS

Inactive ingredients:

- dimethylsiloxane/methylvinylsiloxane (cross-linked) elastomer
- silica - colloidal anhydrous
- polyethylene
- barium sulfate
- iron oxide black CI77499

Supplier

Bayer Australia Ltd
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See TGA website (www.ebs.tga.gov.au) for latest Australian Consumer Medicine Information.

See MEDSAFE website (www.medsafe.govt.nz) for latest New Zealand Consumer Medicine Information.

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