

MIRENA[®] (Mi-RAY-na)

intrauterine levonorgestrel 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. This is surrounded by a membrane (skin) made of dimethylsiloxane/methylvinylsiloxane (cross-linked) elastomer.

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

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

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 oestrogen 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 oestrogen 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 oestrogen 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 also an intrauterine contraceptive device)
- affecting the movement of sperm inside the womb, preventing fertilisation.

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.

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 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 device after “EXP” (e.g. 11 09 refers to November 2009). The expiry date refers to the last day of that month.

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

- your doctor should tell you about the benefit, risk and side effects during use with Mirena
- your doctor should give you a complete physical examination before you start to use Mirena. The check-up should include a gynaecological examination, pelvic examination, examination of the breasts and cervical smear
- Pregnancy and sexually transmitted disease should be

excluded on history and examination, and by further tests if clinically appropriate before insertion. Genital infections have to have been successfully treated.

Your doctor will need to determine the position and the size of your womb.

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

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

- unexplained vaginal bleeding
- abnormal cervix or womb or fibroids which distort the cavity of the womb
- a progestogen dependent tumour
- current or recurrent pelvic inflammatory disease
- any condition associated with increased susceptibility to infections
- a lower genital tract infection
- postpartum endometritis
- you have had an infection of the womb following an abortion in the last three months
- an infection of the cervix (neck of the womb)
- cell abnormalities in the cervix
- cancer or suspected cancer of the cervix or womb
- acute liver disease or liver tumour

Mirena may be used with caution after specialist consultation or your doctor may consider removal of the system if any of the following conditions exist or arise for the first time:

- migraine, or asymmetrical visual loss
- exceptionally severe headache
- jaundice

- marked increase of blood pressure
- severe disease of the arteries such as stroke or heart infarction
- congenital heart disease or valvular heart disease at risk of infective inflammation of the heart muscle. (In such patients antibiotic preventative medication should be given when Mirena is inserted or removed)
- an infection of the womb after delivery
- an ectopic pregnancy or a history of ovarian cysts

In women using contraceptive pills containing progestogen only, some recent studies indicated that there may be a slightly increased risk in venous blood clots, but the results were not very certain.

However you should see your doctor immediately if you have any symptoms or signs of clots. Such symptoms or signs can include:

- one sided leg pain and/or swelling
- sudden severe pain in the chest, whether or not it radiates to the left arm
- sudden breathlessness
- sudden onset of coughing
- any unusual, severe prolonged headache,
- slurred speech or speech difficulties
- weakness or very marked numbness suddenly affecting one side or one part of the body.

Symptoms or signs indicating blood clots in the vessels of your eye are: unexplained partial or complete loss of vision, double vision or any other unexplained disturbances in your eyesight.

It is still under discussion whether varicose veins and superficial

thrombophlebitis (inflammation of a vein with a clot formation) are associated with venous blood clotting.

In diabetic users, the blood glucose concentration should be monitored. However there is no need to alter the therapeutic regimen of Type 1 diabetics using Mirena.

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. Should breast cancer be diagnosed then removal of Mirena should be considered.

Mirena should not be the first choice of contraception in young women who have not had a baby.

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 (carry the foetus outside of your womb).

If you have not told your doctor about any of the above, tell him/her 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.

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 by a professional, experienced in the insertion of intrauterine devices.

When to use it

The system should be inserted either during your period or 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 abortion as long as there are no genital infections. It should not be used until six weeks after delivery.

When Mirena is used to protect the lining of the womb during oestrogen 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 fitted. This is normal and your doctor will tell you to rest for a while. In very rare cases during fitting, part or all of the system could penetrate the wall of

the womb. If this happens the Mirena needs to be removed.

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

Rarely, most often during insertion Mirena can perforate the wall of the womb. If this happens the IUS must be removed as soon as possible. **If you experience excessive pain or bleeding tell your doctor.**

If you are breastfeeding

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

WHILE USING MIRENA

You are protected from pregnancy as soon as the system is fitted.

You should have the system checked usually 6 weeks after it is fitted, again at 12 months and then once a year until it is removed. It can stay in place for five years.

The muscular contractions of the womb during menstruation may sometimes push the IUS out of place or expel it. Possible symptoms are pain and abnormal 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.

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. An unusual increase in the amount of bleeding during your period might be a sign that this has happened. Tell your doctor if there are any unexplained changes in your bleeding pattern.

It is very rare to become pregnant while using Mirena. However if you become pregnant while using Mirena, it is possible that you could carry the foetus outside of your womb (an **ectopic pregnancy**).

The risk of this happening is lower than for women using no contraception.

However this 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
- 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, go to your doctor.

- You should also go to 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.
- Your doctor can remove the system at any time and removal is easy. Unless you plan to have a new system or an intrauterine device fitted immediately, it is important to use another form of contraception in the week leading up to the removal. Intercourse during this week could lead to pregnancy after Mirena is removed.
- The Mirena system and insertion technique have 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. Pelvic infections in IUS users are often related to sexually transmitted diseases. The risk of infection is increased if you or your partner have had several sexual partners. When having sex with anybody who is not a long-term partner, a condom should be used to minimize the risk of infection with HIV, hepatitis B and other STDs. Pelvic infections must be treated promptly. Pelvic infection may impair fertility and increase the risk of extrauterine pregnancy in the future. Mirena must be removed if there are recurrent pelvic infections or if an acute infection does not respond to treatment within a few days. Tell your doctor without delay if you have persistent lower abdominal pain, fever, pain in conjunction with

sexual intercourse or abnormal bleeding.

- 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 oestrogen replacement therapy, a non-bleeding pattern is likely to develop during the first year of use.

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.

With Mirena side effects are most common during the first months after the system is fitted 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 and they worry you.

This list includes the more common side effects of your medicine.

- nervousness
- depressed mood
- lower abdominal or back pain
- pelvic pain
- headache
- nausea
- acne or other skin problems
- tender or painful breasts
- a feeling of sickness
- period pain
- vaginal discharge
- inflammation of the vagina
- water retention
- weight gain
- decreased libido
- expulsion of the IUS
- benign ovarian cysts

The list below includes serious side effects that may require medical attention.

- You have lower abdominal (tummy) pain especially if you have missed a period or have unexpected bleeding. This may be a sign of an ectopic pregnancy
- You think you are reacting badly to Mirena or are having any other problem
- You no longer feel the threads in your vagina.
- You can feel the lower end of the Mirena system
- You think you may be pregnant
- You have persistent abdominal pain, fever or unusual discharge from the vagina.

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.

PRODUCT DESCRIPTION

What it looks like

Mirena is a small, white coloured T-shaped plastic system with black threads attached to the vertical arm.

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

Ingredients

Active ingredients:

- Mirena – 52 mg of levonorgestrel per implant

Inactive ingredients:

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

Supplier

Made in Finland for:

Bayer Australia Limited
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875 Pacific Highway
Pymble NSW 2073

Bayer New Zealand Limited
3 Argus Place, Hillcrest,
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Australian Registration Number:

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See TGA website (www.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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