

MIRENA[®]

(intrauterine levonorgestrel delivery system)

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

The information in this leaflet is only a summary and is not a complete statement about MIRENA. Your doctor has more detailed information relating to you, your medical history and this system and you should consult your doctor if you have any concerns about using MIRENA.

Please read this leaflet carefully and keep it, as you may need to read it again. Please contact your doctor if you have any questions about your treatment with MIRENA or if you have any difficulties whilst using MIRENA.

WHAT IS MIRENA

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 sulphate 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.

WHAT IS MIRENA USED FOR

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 day) over a period of five years or until it is removed.

BEFORE YOU START USING MIRENA

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

You should not use Mirena if:

- You are sensitive to the hormone levonorgestrel or any component of the system
- you are pregnant or suspect you may be
- you have any unexplained vaginal bleeding

- you have an abnormal cervix or womb or fibroids which distort the cavity of the womb
- you have or have ever had a progestogen dependent tumour
- you have current or recurrent pelvic inflammatory disease
- you have any condition associated with increased susceptibility to infections
- you have a lower genital tract infection
- you have postpartum endometritis
- you have had an infection of the womb following an abortion in the last three months
- you have an infection of the cervix (neck of the womb)
- you have cell abnormalities in the cervix
- you have cancer or suspected cancer of the cervix or womb
- you have 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 because of the possibility of more sexual partners and an increased risk of infections. Pelvic infection may impair fertility and increase the risk of ectopic pregnancy.

Before you start using Mirena

- 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.

INSERTION OF MIRENA

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 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

All medicines carry some risk of side effects. With MIRENA these 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. Apart from menstrual changes, possible side effects might include:

- 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

If while using MIRENA, you experience any unwanted effects or symptoms which may be due to MIRENA (whether or not it is mentioned), please tell your doctor as soon as possible.

You may need medical treatment if you experience any of the following unwanted effects:

- 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.

WHAT DOES MIRENA LOOK 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.

HOW DOES MIRENA WORK

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

OTHER IMPORTANT INFORMATION

- The batch number and expiry date are marked on the carton. The system should not be used after the expiry date.
- If you have further questions on the use of MIRENA, or are unsure of any of the above information, please see your doctor who will be able to assist you.

Name and Address of the Sponsor

BAYER AUSTRALIA
LIMITED
ABN 22 000 138 714
875 Pacific Highway
PYMBLE NSW 2073
Australia

Australian Registration

Number: AUST R 73027

Bayer New Zealand Limited
3 Argus Place
Hillcrest, Northshore 0627
New Zealand

Date of preparation:

September 2007

® Registered trademark of the
Bayer Group, Germany

