

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using MIRENA?

MIRENA is an intrauterine device which is inserted into the uterus. It contains the active ingredient levonorgestrel. MIRENA is used as a long term and reversible method of contraception, treatment of excessive menstrual bleeding and excessive growth of the lining of the womb during hormone replacement therapy. For more information, see Section [1. Why am I using MIRENA?](#) in the full CMI.

### 2. What should I know before I use MIRENA?

Do not use if you have ever had an allergic reaction to levonorgestrel or any of the ingredients listed at the end of the CMI, if you are pregnant or plan to become pregnant, if you have medical conditions that affect the female reproductive organs in particular the womb or the pelvis or certain tumours.

**Talk to your doctor if you have any other medical conditions or take any other medicines.**

For more information, see Section [2. What should I know before I use MIRENA?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with MIRENA and affect how it works. The main types of medicines that interfere with how MIRENA works include HIV treatments, Hepatitis C virus treatments, antifungals, certain antibiotics, medicines to treat epilepsy and medicines to treat high blood pressure, chest pain and or irregular heartbeats.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use MIRENA?

MIRENA is inserted and removed by a professional, experienced in the use of intrauterine devices. More information can be found in Section [4. How do I use MIRENA?](#) in the full CMI.

### 5. What should I know while using MIRENA?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Wait about 48 hours after having MIRENA inserted before having sexual intercourse.</li><li>• Remind any doctor, dentist or pharmacist you visit that you are using MIRENA.</li><li>• Have regular checkups with the doctor to ensure MIRENA is in place</li><li>• After each menstrual period check that the device is in place by feeling for the thin threads attached to the lower end of the system</li></ul>
<b>Things you should not do</b>	Do not pull on the removal threads because you may accidentally pull the MIRENA system out
<b>Driving or using machines</b>	Be careful before you drive or use any machines or tools until you know how MIRENA affects you.
<b>Looking after your medicine</b>	Store it in a cool dry place away from moisture, heat or sunlight where the temperature stays below 30°C

For more information, see Section [5. What should I know while using MIRENA?](#) in the full CMI.

### 6. Are there any side effects?

**Less serious side effects** may include period changes, tender or painful breasts, itching, redness or swelling of the vagina, mood changes, headache, acne.

**Serious side effects** that require immediate medical attention include: signs of allergy, excessive abdominal pain or vaginal bleeding, fever, chills or generally feeling unwell.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# MIRENA<sup>®</sup> (Mi·RAY·na)

Active ingredient(s): [*levonorgestrel intrauterine delivery system*]

## Consumer Medicine Information (CMI)

This leaflet provides important information about using MIRENA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using MIRENA.**

Where to find information in this leaflet:

- [1. Why am I using MIRENA?](#)
- [2. What should I know before I use MIRENA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use MIRENA](#)
- [5. What should I know while using MIRENA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using MIRENA?

**MIRENA is an intrauterine device (IUD) which contains the active ingredient levonorgestrel** a hormone used in many contraceptive pills.

The hormone is carried in a small T-shaped frame made from plastic. There are two fine threads (removal strings) attached to the bottom of the frame.

The purpose of the T-body is to adjust the system to the shape of the womb (uterus). The vertical arm of the white T-body carries a drug reservoir containing levonorgestrel which is gradually released into the womb. MIRENA may be used for

- long acting reversible contraception
- treatment of heavy menstrual bleeding (menorrhagia)
- protection from endometrial hyperplasia (excessive growth of the lining of the womb) during hormone replacement therapy.

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 estradiol. 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.

Levonorgestrel 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**

### 2. What should I know before I use MIRENA?

- Before you can begin using MIRENA, your doctor will ask you some questions about your personal health history and that of your close relatives.
- About 2 in a 1000 women correctly using MIRENA become pregnant in the first year.
- About 7 in a 1000 women correctly using MIRENA become pregnant in five years.
- About 7 in a 1000 women correctly using MIRENA become pregnant during a 3 year period of use beyond 5 years (Years 6-8)

### Warnings

**Do not use MIRENA if:**

- you are allergic to levonorgestrel, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you are pregnant or suspect you may be pregnant
- you have, or 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 tumours
  - 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)
- cancer or suspected cancer of the cervix or womb
- tumours which depend on progestogen hormones to grow
- unexplained abnormal uterine bleeding
- increase susceptibility to infections

**Check with your doctor if you:**

- were born with heart disease (congenital) or valvular heart disease
- have diabetes, there is generally no need to alter your diabetic medication while using MIRENA but this may need to be checked by your doctor. In diabetic users of MIRENA, the blood glucose concentration should be monitored
- have epilepsy, seizures can occur during placement or removal

**Mirena may be used with caution after specialist consultation, or removal of the system should be considered if any of the following conditions exist or arise for the first time:**

- migraines with visual disturbances or other symptoms this might be a sign 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.

**MIRENA and physical examinations**

- Before your doctor inserts MIRENA intrauterine system, they may perform physical examinations including cervical smear test (Pap smear), pelvic examination and examination of the breasts.
- 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

**Pregnancy and breastfeeding**

**Do not use this product if you intend to get pregnant, think you may be pregnant or are pregnant.** If you become pregnant when using MIRENA contact your doctor immediately. It is recommended to remove the MIRENA as it may increase the risk of miscarriage and preterm labor if

it is left in. However the removal procedure may cause a miscarriage.

If MIRENA cannot be removed, talk with your healthcare provider about the benefits and risks of continuing the pregnancy, and possible effects of the hormone on the developing baby.

It is not known if MIRENA can cause long-term effects on the foetus if it stays in place during a 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.”

**Talk to your doctor if you are breastfeeding or intend to breastfeed.** There is a small amount of levonorgestrel that will be absorbed by your baby if you breastfeed whilst using MIREANA. This is a smaller amount absorbed by babies in comparison to when the mother is using the minipill. There has been extensive experience with the minipill during breastfeeding, indicating no harmful effects to breastfed babies.

**3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy 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 heart beats	Verapamil Diltiazem
Medicines to treat epilepsy	Carbamazepine, topiramate, oxcarbazepine, phenytoin, barbituates, primidone, felbamate
Antibiotics	Rifampicin, rifabutin Macrolide antibiotics (e.g. clarithromycin, erythromycin)
HIV treatments	Efavirenz, nevirapine
Hepatitis C Virus treatments	Boceprevir, telaprevir
Antifungals	Ketoconazole, itraconazole, voriconazole, fluconazole, griseofluvin
Other	St John’s Wort Grapefruit juice

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MIRENA.**

## 4. How do I use MIRENA?

Mirena is inserted into the uterus and removed by a healthcare professional, experienced in the use of intrauterine devices.

You may feel faint after the system is inserted. This is normal and your doctor will tell you to rest for a while afterwards.

### When to insert MIRENA

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 provided that there are no genital infections. 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.

### For how long can MIRENA be used?

Mirena is effective for 8 years for prevention of pregnancy (contraception). Are you using Mirena for this reason? If so, your Mirena should be removed or replaced after 8 years at the latest.

Mirena is effective for 5 years for heavy menstrual bleeding (idiopathic menorrhagia). Are you using Mirena for one of these reasons? If so, your Mirena should be removed or replaced when the heavy menstrual bleeding or painful menses return or after 8 years at the latest.

Mirena is effective for protection from excessive growth of the lining of the womb (endometrial hyperplasia) during estrogen replacement therapy for 5 years. Are you using Mirena for this reason? If so, your Mirena should be removed after 5 years.

If you like, you may have a new Mirena inserted at the same appointment when the old one is removed.

## 5. What should I know while using MIRENA

### Things you should do

- Wait about 48 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.

- Infrequently, 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 at least once a year until it is removed.
- If you received a patient reminder card from your doctor, bring this with you to every scheduled appointment.
- In addition, you should contact your doctor if any of the following occurs
  - You no longer feel the threads in your vagina
  - You can feel the lower end of the system
  - You think you may be pregnant
  - You have persistent abdominal pain, fever or unusual discharge from the vagina
  - You or your partner feel pain or discomfort during sexual intercourse
  - There are sudden changes in your menstrual periods (for example if you have little or no menstrual bleeding and then you start having persistent bleeding or pain, or you start bleeding heavily
  - You have other medical problems such as migraine headaches or intense headaches that recur, sudden problems with vision, jaundice or high blood pressure
  - You experience any of the conditions mentioned in section "before you use MIRENA)
- 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. MIRENA does not protect against HIV infection (AIDS) and other STIs.
- After each menstrual period, you should feel for the two thin threads attached to the lower end of the system. Your doctor will show you how to do this. If you cannot feel the threads, consult your doctor.
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### Things you should not do

- Do not pull on the removal threads because you may accidentally pull the MIRENA system out. If tampons or menstrual cups are used, you should change them with care so as not to pull the threads of Mirena.

### Removal

- 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.

### Expulsion

- 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 or have heavy periods.

- If the IUS is out of place, it may not work as intended. If the IUS is expelled you are not protected against pregnancy anymore.
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- Possible symptoms of an expulsion are pain and increased amount of 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. 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.

### **Bleeding patterns**

- You may have frequent spotting or light bleeding in addition to your periods for the first 3-6 months after you have MIRENA inserted.
- You will likely 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 do not have your period and have other symptoms of pregnancy (for example nausea, tiredness, breast tenderness) you should see your doctor for an examination and have a pregnancy test.
- 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**

- Perforation or penetration of the wall of the womb may occur, most often during placement of MIRENA, although it may not be detected until sometime later.
- The risk of perforation increases if MIRENA is inserted while you are breastfeeding and up to 36 weeks after giving birth). The risk may also be increased if you have a fixed retroverted uterus (tilted womb).
- If you experience excessive pain or bleeding after insertion, tell your doctor immediately.
- If this perforation occurs MIRENA must be removed as soon as possible. You may need surgery to have MIRENA removed.

### **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.
- About 1 in a 1000 women correctly using MIRENA have an ectopic pregnancy per year.

- Woman who already had an extrauterine pregnancy, surgery of the tubes from the ovaries to the womb or a pelvic infection carry a higher risk.
- 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

### **Pelvic infections**

- As with other gynaecological or surgical procedures, severe infections or sepsis can occur following MIRENA insertion.
- 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.
- You have an increased risk of pelvic infections if you have multiple sexual partners, STIs or a history of pelvic inflammatory disease.
- 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.

### **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.
- Available data is not conclusive for whether MIRENA increases your risk for breast cancer when it is being used for 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

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how MIRENA affects you.**

MIRENA may cause dizziness in some people especially immediately after insertion.

### Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly before it is inserted by your healthcare professional.

**Store it in a cool dry place away from moisture, heat or sunlight where the temperature stays below 30°C**

Do NOT store it in the bathroom or near a sink, or in the car or on window sills.

**Keep it where young children cannot reach it.**

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

**Side effects are most common during the first months after the system is placed and decrease as time goes on.**

### Less serious side effects

Less serious side effects	What to do
<b>Reproductive System related</b> <ul style="list-style-type: none"> <li>decreased libido</li> <li>bleeding changes including increased or decreased menstrual bleeding, spotting, infrequent or light periods, absence of bleeding</li> <li>genital tract infection</li> <li>ovarian cyst</li> <li>tender or painful breasts</li> <li>period pain</li> <li>itching, redness and/or swelling of the vagina</li> <li>vaginal discharge</li> <li>lower abdominal/pelvic pain or back pain</li> </ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

<b>Mood related</b> <ul style="list-style-type: none"> <li>nervousness</li> <li>depressed mood, mood swings</li> </ul>	
<b>Other</b> <ul style="list-style-type: none"> <li>headache, migraine</li> <li>nausea</li> <li>acne</li> <li>excessive hairiness</li> <li>hair loss</li> <li>expulsion of MIRENA</li> </ul>	

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>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</li> <li>seizure in an epileptic patient</li> <li>excessive abdominal pain or vaginal bleeding</li> <li>fever, chills or generally feeling unwell</li> </ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What MIRENA contains

<b>Active ingredient (main ingredient)</b>	52 mg of levonorgestrel
<b>Other ingredients</b>	<ul style="list-style-type: none"> <li>dimethylsiloxane/methylvinylsiloxane (cross-linked) elastomer</li> <li>silica - colloidal anhydrous</li> <li>polyethylene</li> </ul>

<b>(inactive ingredients)</b>	<ul style="list-style-type: none"><li>• barium sulfate</li><li>• iron oxide black CI77499</li></ul>
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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

**Do not take this medicine if you are allergic to any of these ingredients.**

### **What MIRENA 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.

(AUST R 73027)

### **Who distributes MIRENA**

Bayer Australia Ltd  
ABN 22 000 138 714  
875 Pacific Highway  
Pymble NSW 2073

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