



YOUR QUESTIONS ANSWERED

This booklet is intended as a resource for women who have been prescribed Mirena.

 **Mirena**[®]
52 mg levonorgestrel

About this booklet

It may be the first time you're using Mirena or it may be time to have your device removed and replaced. Your doctor or nurse has given you this booklet to help answer some of your questions.

Keep it in a safe place so you can refer to it at any time, and always speak to your healthcare provider if you're unsure or have any other questions.

This booklet is one of a range of resources and tools available to help **you** in a shared decision-making discussion with your healthcare team.

What is Shared Decision Making?

Healthcare provider

The expert on health tests, treatments and providing the clinical perspective.



Patient

The expert on what matters to them through a lived experience perspective.



"Not deciding alone"

Shared Decision Making is having a say in your own healthcare.

Ensuring you are in the driver seat when making important healthcare choices

Shared decision-making is an essential part of your care. The shared decision-making approach involves open communication, active participation, and mutual respect. Your healthcare providers may be the experts on health tests and treatments, but you are the expert on what matters to you.

Shared decision-making is about not having to make medical decisions alone. It allows you to be actively involved in decisions about your health and care. By sharing information, discussing treatment options and considering your preferences and values, healthcare providers can work with you to make decisions that are tailored to your unique needs and circumstances.

Remember, you are the most important part of the team managing your health. The more you communicate with your doctor and other members of the healthcare team, the better you will be able to manage your own health.

Adapted from Jull et al, 2019.

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About Mirena

What is Mirena?¹

Mirena is a type of intrauterine device (IUD) which is fitted by an experienced healthcare professional (HCP) into your uterus. It belongs to the long-acting reversible group of contraceptive options.

It has a small, T-shaped frame made from a soft, flexible plastic. Around the stem of the frame is a cylinder containing a hormone called levonorgestrel and there are 2 fine threads attached to the base of the frame. These threads allow your doctor to remove your Mirena when necessary.



What can Mirena be prescribed for?^{1,2}

Mirena has been available for more than 20 years in Australia and has 3 approved uses. It can be used for:



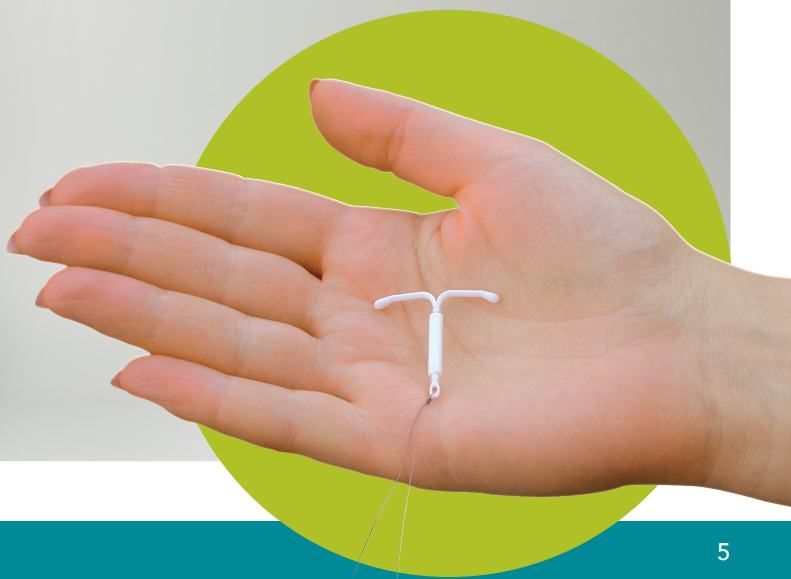
long-acting reversible contraception



treatment of heavy menstrual bleeding (menorrhagia) when no cause can be found



protection from endometrial hyperplasia (excessive thickening of the lining of the uterus as part of hormone therapy used during menopause).





For how long can my Mirena be used?^{1,2}

- Each Mirena is approved for up to 8 years of continuous use for contraception.
- If you're using Mirena to manage heavy periods, it's approved for up to 5 years of use. However, if your bleeding is still being well managed and you're also relying on the device for contraception, it may be possible to wait for 8 years before it's removed and replaced. Your doctor will help you decide if this is an appropriate option for you.
- If your Mirena is protecting the lining of your uterus as part of your menopausal hormone therapy (MHT), it must be removed and replaced every 5 years.
- Mirena can be removed by a healthcare professional at any time if you change your mind or your situation changes. However, it's important to speak to your doctor about the timing of removal if you aren't planning to try for a pregnancy immediately.

What are the ingredients in Mirena?^{1,3}

Mirena contains a hormone called levonorgestrel which is a type of progestogen. Levonorgestrel is also found in some oral contraceptive pills and is similar to the progesterone hormone made by your body.

The T piece frame also contains barium sulfate, which is a contrast medium so your doctor can view it on an X-ray if necessary.

The 2 fine threads attached to the base of the frame are made of iron oxide and polyethylene.

How is Mirena fitted?¹

Having your Mirena fitted in your uterus requires a small procedure performed by a healthcare professional. Speak to your doctor about what to expect.

Can all women use Mirena?¹

As with any medication or treatment, Mirena may not be suitable for everyone. Your doctor has prescribed Mirena for you, but if your situation changes while your Mirena is in place, ask for advice.

Are there possible side effects when using Mirena?¹

All medicines can have side effects but not everyone experiences them. For those that do, most side effects are minor and temporary.

Some possible side effects of Mirena that have been reported include:

- pain, bleeding, dizziness and fainting during placement or removal of Mirena
- genital tract infection
- ovarian cyst
- 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 (falling out) of Mirena.

Don't be alarmed by this list, as you may not experience any of these side effects, but do speak to your doctor or nurse if you are concerned at any time.

For women who do experience side effects, they tend to be most common during the first months after Mirena is fitted and decrease as time goes on.

For more information, including things to tell your doctor before and while you are using Mirena, refer to the Consumer Medicine Information leaflet available from the TGA website at www.ebs.tga.gov.au or by calling 1800 008 757.

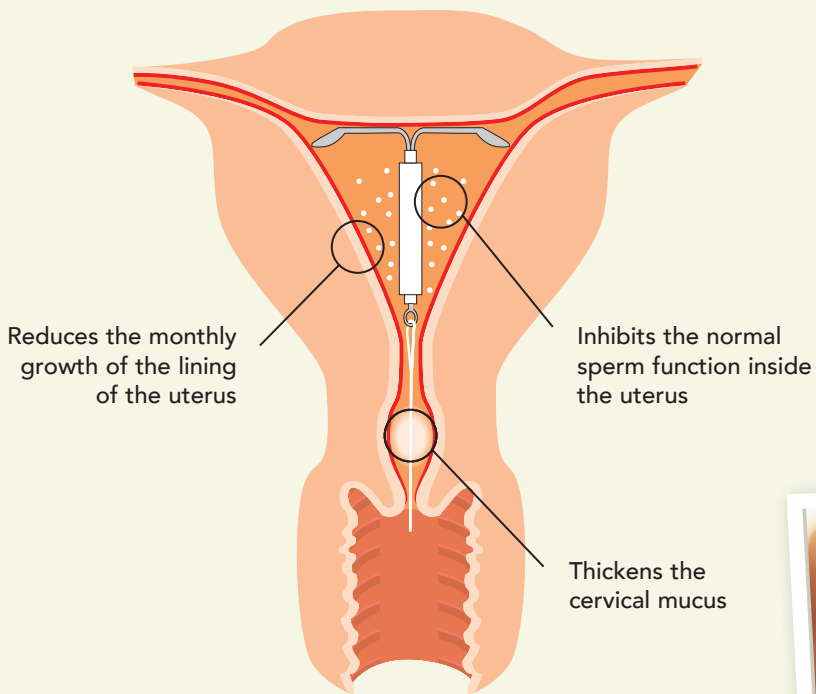
About contraception

For women who have been prescribed Mirena for long-acting reversible contraception.¹

How does Mirena prevent pregnancy?¹

The levonorgestrel in Mirena prevents pregnancy by:

- making the mucus in the opening to the uterus, the cervical canal, thicker so that sperm can't get through to fertilise the egg
- affecting the movement of sperm inside the uterus, preventing fertilisation
- reducing the monthly development of the lining of the uterus.



Do I need to use extra contraception after Mirena is fitted?^{1,4}

If your Mirena is fitted during the first 7 days of your cycle it will provide contraception straight away. This advice may be different if you are changing from another contraceptive method or if your Mirena is fitted at another time during your cycle. Your doctor will provide advice specific to your situation.

You should wait at least 48 hours after your Mirena has been fitted before having sex, to minimise the risk of infection.

Does Mirena protect against sexually transmitted infections (STIs)?²

No, Mirena doesn't protect against STIs. Barrier methods (i.e. condoms) should be used to prevent the transmission of STIs.

What if I want to become pregnant or want to remove Mirena for other reasons?^{1,2}

Mirena can be removed at any time by your doctor or nurse. Although it is a long-acting contraceptive when it's fitted, using Mirena doesn't affect your future fertility and after removal, you can begin trying to fall pregnant immediately. The chance of falling pregnant at 1 year is similar to that in women who do not use contraception.

If contraception is still required after your Mirena is removed, make sure you discuss another contraceptive method with your doctor beforehand.



Can I breastfeed while using Mirena?^{1,2,5}

Speak to your doctor or midwife if you are breastfeeding – they can advise whether Mirena is suitable for you and when to have it fitted after your baby is born.

Progestogen-only methods of contraception, such as Mirena, don't appear to affect the quantity or quality of breast milk.

When Mirena is used while breastfeeding, breastmilk contains a very small amount of levonorgestrel and this will be transferred to baby during feeding. The amount of levonorgestrel in breastmilk is lower than when taking the mini-pill, which is another progestogen-only contraceptive that's often prescribed after giving birth. Extensive experience with the mini-pill during breastfeeding suggests there are no harmful effects to breastfed babies.



About Heavy Menstrual Bleeding (HMB)

For women who have been prescribed Mirena as treatment for HMB when no cause of the bleeding can be found.¹

What is HMB?⁶

Menstrual bleeding is considered heavy when it interferes with a woman's physical, social and/or emotional quality of life. It's a common condition, affecting about 1 in 4 women of reproductive age.

Periods are a very personal experience and women who have always had heavy periods may believe theirs are normal. Symptoms such as flooding through clothing, being unable to leave the house on the heaviest days and having to change pads and tampons frequently (including at night) may indicate heavy menstrual bleeding.

What causes HMB?⁶⁻⁸

There are a number of possible causes, including hormone imbalances and gynaecological conditions such as fibroids, polyps or thickening of the lining of the uterus, called endometrial hyperplasia. Clotting abnormalities and some medications can also cause HMB. However, in nearly 50% of cases, no cause can be found.



How does Mirena work to treat HMB?^{1,6}

Mirena helps treat HMB by slowly releasing levonorgestrel within the uterus, which suppresses the way in which the cells in the lining respond to estrogen. This stops the uterus lining growing each month, which reduces the volume and duration of menstrual bleeding.

Australian Guidelines recommend Mirena as an effective way to manage HMB medically without needing surgery.

About Menopausal Hormone Therapy (MHT) or Hormone Replacement Therapy (HRT)

For women who have been prescribed Mirena for protection from excessive growth of the lining of the uterus, called endometrial hyperplasia, during MHT (or HRT).¹



What is menopause?^{9,10}

Menopause is a woman's final period. It happens when there are no eggs left, either because of the natural ageing process or due to surgery or cancer treatment. Most women in Australia naturally reach menopause between the ages of 45–55 years.

In the years leading up to menopause, gradual changes occur as the ovaries produce lower amounts of hormones, particularly estrogen. This is called perimenopause. During this time, some women notice their periods changing but it's still possible to become pregnant, which means contraception remains important.

Apart from changes in bleeding patterns, other symptoms of perimenopause and

menopause can occur due to the decrease in estrogen. These include hot flashes and night sweats, mood changes, sleep problems and other symptoms.

What is MHT (or HRT)?^{1,2,11,12}

MHT (or HRT) is the medical replacement of female hormones to help manage symptoms of menopause when they are interfering with your life.

MHT consists of the hormone estrogen, with or without progestogen. Your doctor will have discussed the type of MHT suitable for you, but if you haven't had a hysterectomy, taking estrogen alone can cause a precancerous condition called endometrial hyperplasia. This is where the lining of the uterus grows excessively and it occurs in as many as 1 in 5 women after 1 year of continuous use of estrogen-only MHT.

The levonorgestrel in Mirena is a progestogen which suppresses this response and can be used to protect the lining of your uterus from the effects of estrogen therapy.



Frequently asked questions

What happens to my periods while I am using Mirena?^{1,13,14}

Mirena will change your periods. Initially you're likely to have an increase in the number of days you experience bleeding each month. Most women have frequent spotting (a small amount of menstrual blood loss) or light bleeding (requiring panty liners) in addition to their periods for the first 3–6 months after Mirena is fitted. This is normal for new users.

Over time, the number of bleeding days and the amount of blood loss each month are likely to reduce gradually. Some women find that their periods stop altogether.

If it's time to have your Mirena removed and replaced, any initial increase in bleeding that you experienced with your first Mirena is unlikely to recur with the same frequency.

When Mirena is removed and is not replaced, your periods can be expected to return to what is normal for you, unless you have reached menopause.

You may find the chart at the back of this booklet useful to record any days of spotting and light bleeding in the weeks or months after your Mirena is inserted so that you can discuss this with your doctor at your first follow-up appointment.

Can I fall pregnant with Mirena in place?^{1,2}

Mirena is over 99% effective at preventing pregnancy. It's rare to become pregnant while using Mirena – fewer than 2 in 1000 women experience this.

Although it is very unlikely, if you're worried that you have become pregnant while using Mirena, see your doctor as soon as possible.

Can I fall pregnant after having my Mirena removed?^{1,2}

Yes, depending on your normal level of fertility. Amongst women who stopped using Mirena to try for a pregnancy, the chance of falling pregnant at 1 year was similar to those who did not use contraception. You could become pregnant during the first few weeks after Mirena is removed.



When should Mirena be fitted?¹

If it's your first time using Mirena, the recommendation is to have it fitted during the first 7 days of your cycle – in other words, within 7 days from the beginning of your period. Having Mirena fitted at another time during your cycle should be discussed with your doctor.

If you're having your existing Mirena replaced, this can be done at any time during your cycle – you don't need to wait for your period. Removal and replacement can be performed at the same appointment.

When Mirena is used to protect the lining of the uterus during menopausal hormone therapy, it can be fitted during the last days of a period or a withdrawal bleed. If you no longer have monthly bleeding, it can be inserted at any time.

How can I check that my Mirena is in place?¹

After each period or about once a month, check that you can feel the 2 fine threads attached to the bottom of your Mirena – your doctor will show you how to do this. Don't tug on the threads though, as you may accidentally pull your Mirena out. If you can't feel the threads, see your doctor.

Do I need to have my Mirena checked regularly by my doctor?¹

You should have your Mirena checked for the first time 4-12 weeks after it's fitted and then at least once a year until it's removed.





Will my Mirena interfere with having sex?^{1,4,15}

Neither you or your partner should feel your Mirena during sex. If you do, avoid having sex or use another type of contraception, like condoms, until your doctor has checked that your Mirena is still in the correct position.

Occasionally it may be possible for your partner to feel the ends of the threads. If this causes concern or discomfort, the length of the threads can be adjusted by your doctor.



Can I use tampons or menstrual cups?^{1,16}

You shouldn't insert anything into your vagina for the first 48 hours after your Mirena is fitted, but after this, yes, you can use them.

Tampons won't change the position or effectiveness of your Mirena, but always change them carefully to avoid accidentally pulling on the threads attached to it. The same applies to changing a menstrual cup.



Can Mirena become dislodged or fall out?^{1,2}

It is possible, but if your Mirena comes out either partially or completely there will likely be signs to alert you. These include an unexpected increase in bleeding, possibly some pain, you or your partner being able to feel the lower end of the device, the threads may seem longer or you may not be able to feel them at all.

It's rare but possible for your Mirena to dislodge without you noticing during your menstrual period, especially if your periods are heavy.

If your Mirena does come out either partially or completely, you won't be protected against pregnancy. Avoid having sex, or use another form of contraception, and see your doctor as soon as you can.

Can Mirena cause perforation?^{1,2}

It's rare, but it can happen during the procedure to fit the device. Fewer than 2 in 1000 women may experience this, although it may not be detected until later. The risk of perforation increases if you've given birth within the last nine months or you're breastfeeding. If you experience excessive pain or bleeding during or after insertion, or at any time while your Mirena is fitted, tell your doctor immediately.

Can Mirena cause pelvic infection?^{1,17}

The risk of a pelvic infection does increase slightly in the first month after your Mirena is fitted simply due to the small procedure that's required.

You should avoid putting anything in your vagina for 48 hours after your Mirena is fitted to minimise this risk. This includes having sex, using tampons or menstrual cups, having a bath and going swimming.

Tell your doctor immediately if you have persistent lower abdominal pain, fever, pain during sex or abnormal bleeding – these may be signs of infection and should be treated promptly.

Can Mirena interact with other medicines I may be taking?¹

Some medicines and Mirena may interact with each other. Tell your doctor or pharmacist if you are taking any other medicines, including those that you get without a prescription from your pharmacy, supermarket or healthfood shop. For more information about medicines that can interact with Mirena, refer to the Consumer Medicine Information leaflet available from the TGA website at www.ebs.tga.gov.au or by calling 1800 008 757.

Does Mirena contain any latex?¹

No. Mirena is completely free of latex and is made from a type of soft, flexible plastic.



Will any of the hormones be absorbed by my body?^{1,2}

Although the hormonal effect of Mirena is mainly localised to inside the uterus, a very small amount of the hormone it contains is absorbed into your blood. Most women of reproductive age will still ovulate because the amount absorbed into the bloodstream isn't enough to affect your natural cycle.

This also means any hormonal side effects are generally mild in nature. They're also more commonly reported in the first few weeks and months of use and usually settle during the first few months.

Can Mirena be seen on X-ray?²

Yes. Mirena can be seen on X-ray and can also be located using ultrasound.

How will I remember when it's time to have my Mirena replaced?¹

There is a Mirena Reminder Card inside the box your Mirena comes in. Ask your doctor to give you this card and record the date. Many doctors also use a reminder system in their records and will send you a message.

Bleeding Pattern Diary

Use the following page to record your bleeding pattern after your Mirena is first fitted. Don't forget to have the diary with you when you call or visit your doctor, because they're likely to ask you about your bleeding patterns. Keeping track of these patterns can help you and your doctor understand how your body is adjusting to Mirena.

You can use these symbols when you enter information in the diary:

- | | |
|--|--|
| X Mirena insertion date | N Normal bleeding (the usual amount of bleeding during your period) |
| S Spotting: less than your normal period. Minimal sanitary protection is needed (i.e. panty liners) | H Heavy bleeding (more bleeding than your normal period) |
| L Light bleeding (less bleeding than your normal period but more than spotting) | • No bleeding at all |

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