



Fictional characters for illustrative purposes only.

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 healthcare professional has given you this booklet to help answer some of your questions.

The information in this booklet does not replace a healthcare professional's advice. Speak to your healthcare professional to find out if Mirena® is right for you.

You can also refer to the Mirena® Consumer Medicine Information available at www.medsafe.govt.nz or scan the QR code.

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 you 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/or other members of the healthcare team, the better you will be able to manage your own health.

Adapted from Jull J, et al. 2021.¹

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About Mirena®

What is Mirena®?^{2,3}

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 is a small, T-shaped frame made from a soft, flexible plastic 3 cm long. 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 healthcare professional to remove your Mirena® when necessary.

When you collect Mirena® from a pharmacy, you'll notice it is supplied in a long thin box as the device comes with its own special insertion tube, used to place Mirena® into your uterus.



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What can Mirena® be prescribed for?^{2,3}

Mirena® was first registered in New Zealand in 1998, and has three indications. It can be used for:



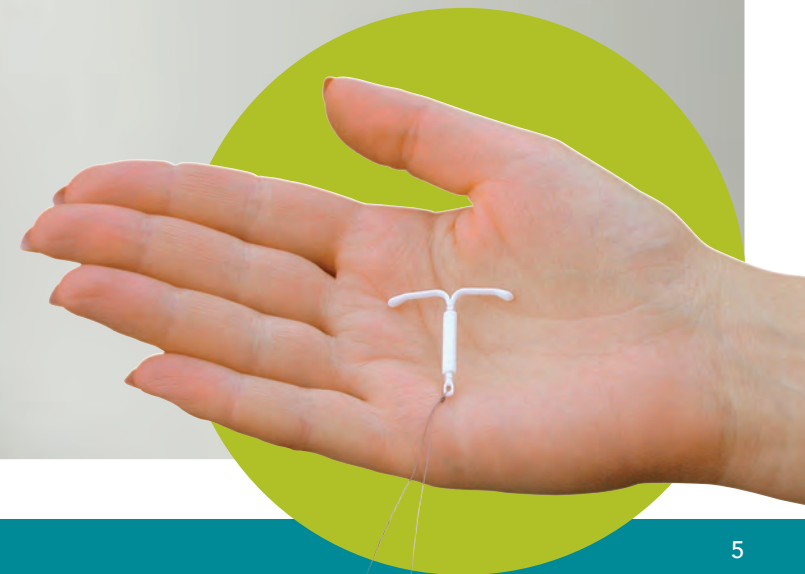
contraception



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



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





How long can Mirena® be used for?^{2,3}

- Mirena® is registered for up to 8 years of continuous use for contraception.
- If you're using Mirena® to manage heavy periods, it's registered 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 up to 8 years before it's removed and replaced. Your doctor or healthcare professional will help you decide if this is an appropriate option for you.
- If your Mirena® is used to protect the lining of your uterus as part of your estrogen 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 healthcare professional about the timing of removal if you aren't planning to try for a pregnancy immediately.

What are the ingredients in Mirena®?²

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.

Mirena® 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.

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How is Mirena® fitted?²

Having your Mirena® fitted in your uterus requires a small procedure performed by a healthcare professional.

The insertion process³

1. To help fit your Mirena® in the correct position, your healthcare professional will perform an examination to determine the size and position of your uterus.
2. Under sterile conditions, your healthcare professional will insert the plastic tube containing Mirena® into your uterine cavity. You may feel some discomfort or cramping at this time.
3. Once Mirena® is in the correct position, your healthcare professional will withdraw the plastic insertion tube, leaving the Mirena® in your uterus. They will then trim the threads of the Mirena®. The threads are there to let you check your Mirena® is still in place and help your healthcare professional remove the system when required.

Speak to your healthcare professional about what else to expect.

Can all women use Mirena®?²

As with any medication or treatment, Mirena® may not be suitable for everyone. Your healthcare professional 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®?²

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



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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.

Immediate side effects after insertion usually disappear after a few hours and side effects experienced during the first months after Mirena® is fitted decrease as time goes on.



For more information, including things to tell your doctor or nurse before and while you are using Mirena®, refer to the Consumer Medicine Information leaflet available from the Medsafe website at www.medsafe.govt.nz or scan the QR code.

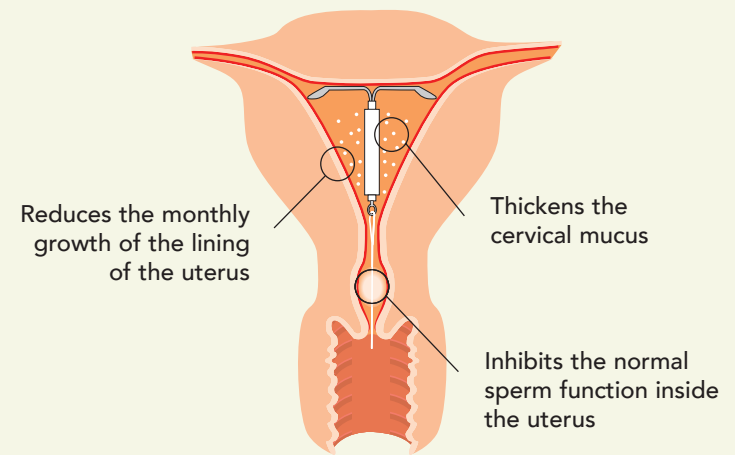
About contraception

For women who have been prescribed or are considering Mirena® as a long term and reversible method of contraception.

How does Mirena® prevent pregnancy?²

Mirena® contains a synthetic hormone called levonorgestrel which is a progestogen. This hormone 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.



How effective is Mirena® for contraception?^{2,4}

Mirena® is one of the most effective and reliable methods of contraception available.⁴ Studies have shown that of 1,000 women who use Mirena® for 1 year, no more than two are likely to become pregnant.² This is similar to female sterilisation.⁴

Once Mirena® is properly fitted, and provided it stays in position, it is registered for up to 8 years of continuous use and the reliability remains over 99% over this time.^{2,4}

Do I need to use extra contraception after Mirena® is fitted?^{2,5}

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 or nurse 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.²

Does Mirena® protect against sexually transmitted infections (STIs)?³

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?^{2,3}

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. 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 or nurse beforehand.

Can I breastfeed while using Mirena®?^{2,3,6}

Speak to your doctor, nurse 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.

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About Heavy Menstrual Bleeding (HMB)

For women who have been prescribed Mirena® as treatment for HMB when no underlying cause of the bleeding can be found.²

What is HMB?⁷

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.



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What causes HMB?⁷⁻⁹

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?^{2,7}

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.

The New Zealand National Guideline for Abnormal Uterine Bleeding recommends Mirena as first line hormonal treatment for heavy menstrual bleeding (HMB) in women without structural causes for HMB and where there is no risk for endometrial pathology.¹⁰

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).²

What is menopause?^{11,12}

Menopause is marked by when a woman's periods stop naturally or she has had medical or surgical therapy that permanently stops her from having a normal cycle. Most women reach menopause between 45–55 years.

There is an interval of a few years before this happens, when gradual changes occur as the ovaries produce lower amounts of hormones and the frequency of ovulation may change. This is called perimenopause. During this time, it may still be possible to become pregnant, so contraception is still important.

Apart from changes in bleeding patterns, other symptoms of perimenopause and menopause can occur due to the decrease in estrogen. These include hot flushes and night sweats, mood changes, sleep problems and other symptoms.

What is MHT (or HRT)?^{2,3,13,14}

MHT (or HRT) is the medical replacement of female hormones to help manage symptoms of menopause such as hot flushes and night sweats, when they are interfering with your life.

MHT consists of the hormone estrogen, with or without progestogen. Your doctor or healthcare professional 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.

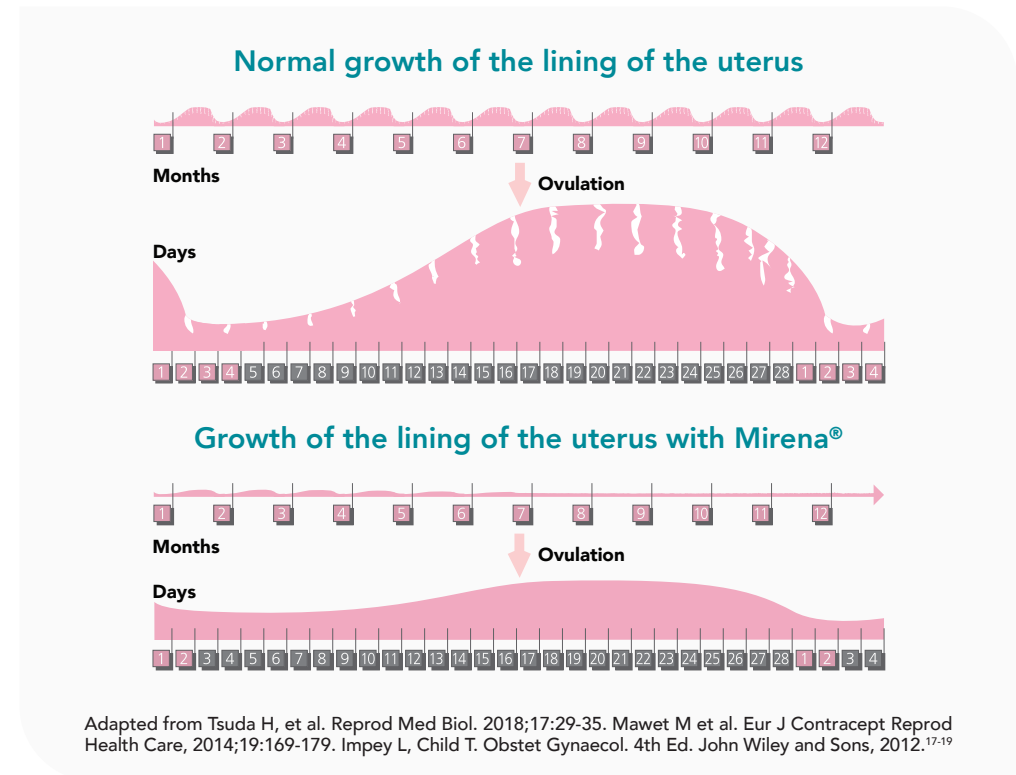


Frequently asked questions

What happens to my periods while I am using Mirena®?^{2,15,16}

Mirena® will affect 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.

However over time, you are likely to have a gradual reduction in the number of bleeding days and in the amount of blood loss each month. Some women eventually 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 or healthcare professional at your first follow-up appointment.

Isn't it abnormal not to have a period?^{2,3}

When using Mirena®, some women find that over time their periods stop altogether. Others find that their bleeding patterns change to a more infrequent, lighter period whilst using Mirena®.

If you find that you do not have periods while using Mirena®, it's because of the effect of the hormone on the lining of your uterus. The thickening of the lining with blood is greatly reduced, and in some women does not happen at all, so there may be very little or no blood to come away as a period.

Since the effect of Mirena® is mainly localised in the uterus, the production of ovarian hormones still remains within normal limits and most women of fertile age will ovulate regularly even though they may not be menstruating.

If you have not had a period for 6 weeks, and you are concerned, you should consider having a pregnancy test. If this is negative, there is no need to have another test unless you have other signs of pregnancy e.g. sickness, tiredness or breast tenderness.

If you are concerned, you should speak with your healthcare professional.

Can I fall pregnant with Mirena® in place?^{2,3}

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 or healthcare professional as soon as possible.

Can I fall pregnant after having my Mirena® removed?^{2,3}

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?^{2,3}

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 or healthcare professional.

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.

After having a baby, Mirena® can usually be inserted from 6 weeks after a vaginal or 'natural' delivery and usually after about 12 weeks if you have had a caesarean section.

Mirena® may also be inserted immediately after a first trimester termination of pregnancy or at the follow up visit after a medical termination of pregnancy, provided there are no genital or pelvic infections.

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.



Is it painful to insert?^{2,3,20}

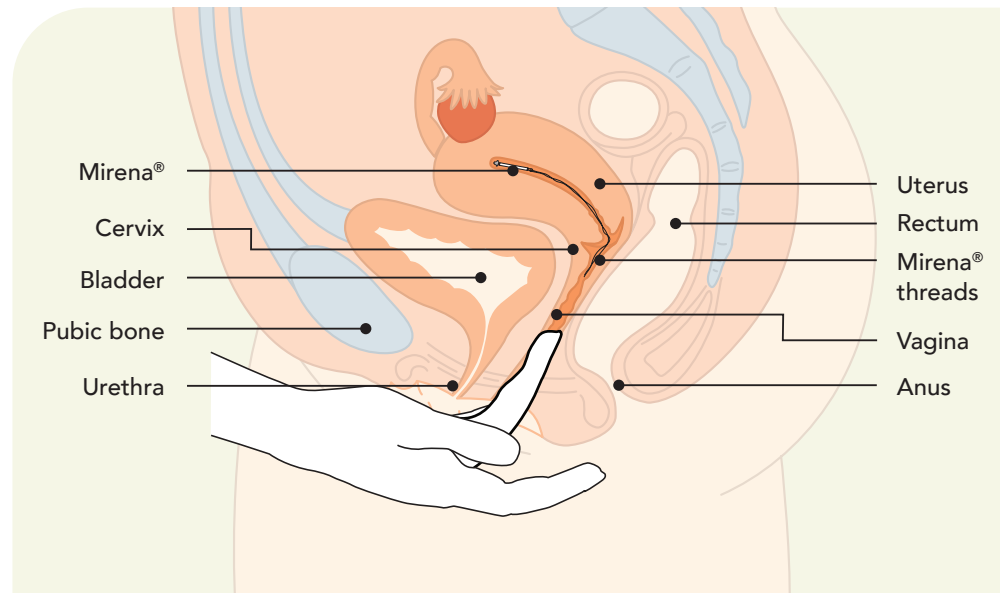
The insertion of Mirena® can be uncomfortable, although half of women experience little or no pain during the procedure. Women who have delivered a baby only via caesarean section or those who have not had children may find it more uncomfortable, and may wish to discuss options for pain relief before the procedure.

How long does insertion take?

Preparations for the insertion usually take about 5 to 10 minutes, and the actual insertion of Mirena® will usually take only a few minutes.

How can I check that my Mirena® is in place?²

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 or healthcare professional 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 or healthcare professional.



Your healthcare professional can teach you how to feel for the strings.

Do I need to have my Mirena® checked regularly by my healthcare professional?²

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. Your healthcare professional will advise you when they would like to see you for an initial follow up visit.

Will my Mirena® interfere with having sex?^{2,5,21}

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 or healthcare professional 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 or healthcare professional.

If Mirena® is fitted within the first 7 days of the menstrual cycle, it will protect against pregnancy as soon as it is inserted. However, it is best to wait about 48 hours before having sexual intercourse.

Can I use tampons or menstrual cups?^{2,22}

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.



Fictional characters for illustrative purposes only.

Can Mirena® become dislodged or fall out?^{2,3}

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 or healthcare professional as soon as you can.

Can Mirena® cause perforation?^{2,3}

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 or healthcare professional immediately.

Can Mirena® cause pelvic infection?^{2,23}

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 have an increased risk of pelvic infections if you have multiple sexual partners, acquire an STI or have 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.

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 or healthcare professional 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?²

Some medicines and Mirena® may interact with each other. Tell your healthcare professional or pharmacist if you are taking any other medicines, including those that you get without a prescription from your pharmacy, supermarket or healthfood shop.

Does Mirena® contain any latex?²

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?^{2,3}

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?³

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?²

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



For more information, including things to tell your doctor or nurse before and while you are using Mirena®, refer to the Consumer Medicine Information leaflet available from the Medsafe website at www.medsafe.govt.nz or scan the QR code.



Fictional characters for illustrative purposes only.

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 healthcare professional, because they're likely to ask you about your bleeding patterns. Keeping track of these patterns can help you and your healthcare professional understand how your body is adjusting to Mirena®.

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

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

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X Mirena® insertion date

S Spotting

L Light bleeding

N Normal bleeding

H Heavy bleeding

• No bleeding at all

Notes

[illegible]This image shows a blank sheet of white paper with horizontal blue lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

MIRENA® (levonorgestrel). MIRENA® is an intrauterine system containing 52 mg levonorgestrel, which is slowly released at an initial rate of 20 mcg/24 hours. MIRENA is a **Prescription Medicine** for contraception and is effective for 8 years for prevention of pregnancy. MIRENA is also a treatment for unexplained heavy menstrual bleeding where no underlying pathology causing excessive bleeding can be found. Mirena is effective for 5 years for heavy menstrual bleeding. MIRENA is effective for 5 years for protection of the lining of the womb when oestrogen therapy is prescribed for menopausal symptoms. MIRENA must not be used during pregnancy, if there is any sign of pelvic or genital tract infection, inflammation or cancer, if there is womb or cervical abnormality, confirmed or suspected hormone-sensitive cancer including breast cancer, undiagnosed abnormal bleeding, active liver disease or if you are allergic to any ingredients in MIRENA. MIRENA should be inserted by a doctor who has been trained in the insertion technique. Removal of MIRENA is recommended if the following medical conditions occur: an increased susceptibility to infections, acute infection not responding to treatment. Migraine or severe headaches, jaundice, increased blood pressure, hormone-sensitive cancer, stroke, severe heart or blood vessel disease, blood clots may occur during MIRENA use, should this happen; your doctor may consider removal of MIRENA. MIRENA should be used with caution if you have diabetes or a heart condition from birth and are at risk of infection. MIRENA must be removed if pregnancy (which might be outside the womb) or puncture of the womb is suspected or if MIRENA is partially expelled. MIRENA does not protect against HIV infections (AIDS) and other sexually transmitted infections. The pattern of side effects, which are more common in the first months of use, should be explained to you. Commonly reported side effects include changes to menstrual patterns, painful menstruation, genital discharge, redness, or itching, headache/migraine, abdominal, breast or back pain, depressed mood, nervousness, nausea, acne, weight changes, decreased libido, excessive hair growth, benign ovarian cysts and expelled device. The possibility of side effects such as puncture of the womb, allergic reactions, bacterial infection of the blood, breast cancer, or pregnancy outside the womb should be discussed with your doctor, pharmacist or health professional. If symptoms persist or you have side effects, see your doctor for advice. MIRENA is a fully funded medicine – a pharmacy charge and normal Doctor's visit fees and insertion fees may apply. MIRENA has both risks and benefits. Use only as directed. Consult your doctor to see if MIRENA is right for you. For more information, read the Consumer Medicine Information available at <https://www.medsafe.govt.nz/Consumers/cmi/m/Mirena.pdf>.

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