

 **Mirena**[®]
(levonorgestrel-releasing
intrauterine system) 52 mg



GETTING READY FOR YOUR BABY?

Now may be the time to think about postpartum birth control. Talk about your options with your healthcare provider and have a plan that works for you.



Mirena[®] is a hormone-releasing IUD (intrauterine device) that prevents pregnancy for up to 8 years. Mirena also treats heavy periods for up to 5 years in women who choose intrauterine contraception.

7 OUT OF 10 PREGNANCIES IN THE FIRST YEAR POSTPARTUM ARE UNINTENDED

If getting pregnant again isn't part of your plan right now, consider having a contraception plan in place before giving birth.



IMPORTANT SAFETY INFORMATION

- If you have a pelvic or genital infection, get infections easily, or have certain cancers, don't use Mirena®. Less than 1% of users get a serious pelvic infection called pelvic inflammatory disease (PID).
- If you have persistent pelvic or stomach pain, or excessive bleeding after placement, tell your healthcare provider (HCP). If Mirena comes out, call your HCP and avoid intercourse or use non-hormonal back-up birth control (such as condoms or spermicide). Mirena may go into or through the wall of the uterus and cause other problems.

MIRENA® is over 99% EFFECTIVE at PREVENTING PREGNANCY

Mirena:

- Prevents pregnancy for up to 8 years
- Is the #1 prescribed IUD* in the U.S.
- Doesn't require a daily routine†
- Can be removed by your healthcare provider at any time if your plans change
- Is estrogen free

†Once a month you'll have to check the threads on your own.

Did you know? You can still get pregnant even while breastfeeding.

Whether or not you choose to breastfeed is between you and your healthcare provider (HCP). However, it is important to know all the facts related to breastfeeding and Mirena.

Mirena is not likely to affect the quality or amount of breast milk or the health of your nursing baby; however, isolated cases of decreased milk production have been reported.

Be sure to discuss with your HCP first, as the risk of Mirena going into the wall of the uterus (becoming embedded) or going through the wall of the uterus is increased if Mirena is inserted while you are breastfeeding.

*Supported by 2019–2021 SHS data.

IMPORTANT SAFETY INFORMATION

- Pregnancy while using Mirena is uncommon but can be life-threatening and may result in loss of pregnancy or fertility.
- Ovarian cysts may occur but usually disappear.

For additional Important Safety Information, please see throughout brochure. Please see [Important Facts](#) on pages 6-9 and the Full Prescribing Information [here](#).

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Learn more about the use of Mirena® in the postpartum period

Mirena is a pill-free, low-maintenance birth control. There's no daily routine. Instead, with Mirena, you will have to check for the threads once a month on your own. When the baby comes, things will likely get busy. Consider talking with your healthcare provider about all your birth control options, including Mirena, before you give birth.

You may be able to get a Mirena immediately after giving birth or at your 6-week checkup.

An IUD is an effective option for postpartum contraception. Mirena is 99% effective at preventing pregnancy, so you can family plan on your own terms.

The risk of perforation is increased if Mirena is inserted while you are breastfeeding, or if you have recently given birth.

The risk of expulsion is increased with insertion right after delivery or second trimester abortion.

IMPORTANT SAFETY INFORMATION

- Bleeding and spotting may increase in the first 3 to 6 months and remain irregular. Periods over time usually become shorter, lighter, or may stop.

Mirena does not protect against HIV or STIs.

Only you and your HCP can decide if Mirena is right for you. Mirena is available by prescription only.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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Some Questions for Your Healthcare Provider

If you are interested in learning more about Mirena[®], the first step is to have a conversation with your healthcare provider.

- How soon can I get Mirena after having a baby?
- Can I use Mirena while breastfeeding?
- Does Mirena start working right away?
- Can I try to get pregnant as soon as Mirena is removed?

Visit Mirena.com for more information and questions to ask your Healthcare Provider about Mirena.

IMPORTANT FACTS ABOUT MIRENA® (LEVONORGESTREL-RELEASING INTRAUTERINE SYSTEM) 52 MG

Mirena does not protect against HIV infection (AIDS) and other sexually transmitted infections (STIs).

This information does not take the place of talking with your gynecologist or other healthcare provider (HCP) who specializes in women's health. If you have any questions about Mirena, ask your HCP.

INDICATIONS FOR MIRENA

Mirena is a hormone-releasing IUD that prevents pregnancy for up to 8 years. Mirena also treats heavy periods for up to 5 years in women who choose intrauterine contraception.

Who might use Mirena?

You might choose Mirena if you:

- want long-term birth control that provides a low chance of getting pregnant (less than 1 in 100)
- want birth control that works continuously for up to 8 years
- want birth control that is reversible
- want a birth control method that you do not need to take daily
- are willing to use a birth control method that is placed in the uterus
- want treatment for heavy periods up to 5 years and are willing to use a birth control method that is placed in the uterus
- want birth control that does not contain estrogen

Do not use Mirena if you:

- are or might be pregnant; Mirena cannot be used as an emergency contraceptive
- have a serious pelvic infection called pelvic inflammatory disease (PID) or have had PID in the past unless you have had a normal pregnancy after the infection went away
- have an untreated genital infection now
- have had a serious pelvic infection in the past 3 months after a pregnancy
- can get infections easily. For example, if you:
 - have multiple sexual partners or your partner has multiple sexual partners
 - have problems with your immune system
 - use or abuse intravenous drugs
- are or suspect you might have cancer of the uterus or cervix
- have bleeding from the vagina that has not been explained
- have liver disease or a liver tumor
- have breast cancer or any other cancer that is sensitive to progesterin (a female hormone), now or in the past
- have an intrauterine device in your uterus already
- have a condition of the uterus that changes the shape of the uterine cavity, such as large fibroid tumors
- are allergic to levonorgestrel, silicone, polyethylene, silica, barium sulfate or iron oxide

Before having Mirena placed, tell your HCP about all of your medical conditions including if you:

- have any of the conditions listed above
- have had a heart attack
- have had a stroke
- were born with heart disease or have problems with your heart valves
- have problems with blood clotting or take medicine to reduce clotting
- have high blood pressure
- recently had a baby or are breastfeeding
- have severe headaches or migraine headaches
- have AIDS, HIV, or any other sexually transmitted infection

Tell your HCP about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Should I check that Mirena is in place?

Yes, you should check that Mirena is in proper position by feeling the removal threads. It is a good habit to do this 1 time a month. If you feel more than just the threads or if you cannot feel the threads, be sure to call your HCP and avoid intercourse or use non-hormonal back-up birth control, as Mirena may not be in the right position and may not prevent pregnancy.

How soon after placement should I return to my HCP?

Call your HCP if you have questions or concerns (see "After placement, when should I call my HCP?"). Otherwise, return for a follow-up 4-6 weeks after placement to make sure Mirena is in the right position.

Can I use tampons or menstrual cups with Mirena?

Yes, tampons or menstrual cups may be used with Mirena. Change tampons or menstrual cups with care to avoid pulling the threads of Mirena. If you think you may have pulled Mirena out of place, avoid intercourse or use a non-hormonal back-up birth control (such as condoms or spermicide), and contact your healthcare provider.

What if I become pregnant while using Mirena?

Call your HCP right away if you think you may be pregnant. If possible, also do a urine pregnancy test. If you get pregnant while using Mirena, you may have an ectopic pregnancy. This means that the pregnancy is not in the uterus. Unusual vaginal bleeding or abdominal pain, especially with missed periods may be a sign of ectopic pregnancy.

Ectopic pregnancy is a medical emergency that often requires surgery. Ectopic pregnancy can cause internal bleeding, infertility, and even death.

There are also risks if you get pregnant while using Mirena and the pregnancy is in the uterus. Severe infection, miscarriage, premature delivery, and even death can occur with pregnancies that continue with an intrauterine device (IUD). Because of this, your HCP may try to remove Mirena, even though removing it may cause a miscarriage. If Mirena cannot be removed, talk with your HCP about the benefits and risks of continuing the pregnancy and possible effects of the hormone on your unborn baby.

If you continue your pregnancy, see your HCP regularly. Call your HCP 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.

How will Mirena change my periods?

For the first 3 to 6 months, your period may become irregular and the number of bleeding days may increase. You may also have frequent spotting or light bleeding, and some women have heavy bleeding during this time. You may also have cramping during the first few weeks. After you have used Mirena for a while, the number of bleeding and spotting days is likely to lessen. For some women, periods will stop altogether. When Mirena is removed, your menstrual periods should return.

In some women with heavy bleeding who are using Mirena, the total blood loss per cycle progressively decreases with continued use. The number of spotting and bleeding days may initially increase but then typically decreases in the months that follow.

IMPORTANT FACTS ABOUT MIRENA® (LEVONORGESTREL-RELEASING INTRAUTERINE SYSTEM) 52 MG (CONT.)

Is it safe to breastfeed while using Mirena?

You may use Mirena when you are breastfeeding. Mirena is not likely to affect the quality or amount of your breast milk or the health of your nursing baby. However, isolated cases of decreased milk production have been reported. The risk of Mirena going into the wall of the uterus (becoming embedded) or going through the wall of the uterus is increased if Mirena is inserted while you are breastfeeding.

Will Mirena interfere with sexual intercourse?

You and your partner should not feel Mirena during intercourse. Mirena is placed in the uterus, not in the vagina. Sometimes your partner may feel the threads. If this occurs, or if you or your partner experience pain during sex, talk with your HCP.

What are the possible serious side effects of Mirena?

- **Ectopic pregnancy and intrauterine pregnancy risks.** There are risks if you become pregnant while using Mirena (see “What if I become pregnant while using Mirena?”).
- **Life-threatening infection.** Life-threatening infection can occur within the first few days after placement. Call your HCP immediately if you develop severe pain or fever shortly after placement.
- **Pelvic inflammatory disease (PID).** Some IUD users get a serious pelvic infection called pelvic inflammatory disease. PID is usually sexually transmitted. You have a higher chance of getting PID if you or your partner has sex with other partners. PID can cause serious problems such as infertility, ectopic pregnancy or pelvic pain that does not go away. PID is usually treated with antibiotics. More serious cases of PID may require surgery, including removal of the uterus (hysterectomy). In rare cases, infections that start as PID can even cause death. Tell your HCP right away if you have any of these signs of PID: long-lasting or heavy bleeding, unusual vaginal discharge, low abdominal (stomach area) pain, painful sex, chills, fever, genital lesions or sores.
- **Perforation.** Mirena may go into the wall of the uterus (become embedded) or go through the wall of the uterus. This is called perforation. If this occurs, Mirena may no longer prevent pregnancy. If perforation occurs, Mirena may move outside the uterus and can cause internal scarring, infection, or damage to other organs and you may need surgery to have Mirena removed. Excessive pain or vaginal bleeding during placement of Mirena, pain or bleeding that gets worse after placement, or not being able to feel the threads may happen with perforation. The risk of perforation is increased if Mirena is inserted while you are breastfeeding, or if you have recently given birth.
- **Expulsion.** Mirena may come out by itself. This is called expulsion. Excessive pain or vaginal bleeding during placement of Mirena, pain or bleeding that gets worse after placement, or not being able to feel the threads may happen with expulsion. You may become pregnant if Mirena comes out. If you think that Mirena has come out, avoid intercourse or use a non-hormonal back-up birth control (such as condoms or spermicide) and call your healthcare provider. The risk of expulsion is increased with insertion right after delivery or second-trimester abortion.

Common side effects of Mirena include:

- **Pain, bleeding or dizziness during and after placement.** If these symptoms do not stop 30 minutes after placement, Mirena may not have been placed correctly. Your HCP will examine you to see if Mirena needs to be removed or replaced.

- **Changes in bleeding.** You may have bleeding and spotting between menstrual periods, especially during the first 3-6 months. Sometimes the bleeding is heavier than usual at first. However, the bleeding usually becomes lighter than usual and may be irregular. Call your HCP if the bleeding remains heavier than usual or increases after it has been light for a while.
- **Missed menstrual periods.** About 2 out of 10 women stop having periods after 1 year of Mirena use. If you have any concerns that you may be pregnant while using Mirena, do a urine pregnancy test and call your HCP. Your periods may stop after 1 year of Mirena use. If you do not have a period for 6 weeks during Mirena use, call your HCP. When Mirena is removed, your menstrual periods should return.
- **Cysts on the ovary.** Some women develop painful cysts on the ovary. These cysts usually disappear on their own in 2-3 months. However, cysts can cause pain and sometimes cysts will need surgery.

Other common side effects include:

- abdominal or pelvic pain
- inflammation or infection of the outer part of your vagina (vulvovaginitis)
- headache or migraine
- vaginal discharge

These are not all of the possible side effects with Mirena.

For more information, ask your HCP. Tell your HCP if you have any side effect that bothers you or does not go away.

Call your HCP for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to Bayer Healthcare Pharmaceuticals at 1-888-842-2937, or www.fda.gov/medwatch.

After placement, when should I call my HCP?

If Mirena is accidentally removed and you had vaginal intercourse within the preceding week, you may be at risk of pregnancy, and you should talk to a HCP. Call your HCP if you have any concerns about Mirena. Be sure to call if you:

- think you are pregnant
- have pelvic pain, abdominal pain, or pain during sex
- have unusual vaginal discharge or genital sores
- have unexplained fever, flu-like symptoms or chills
- might be exposed to sexually transmitted infections (STIs)
- are concerned that Mirena may have been expelled (came out)
- cannot feel Mirena's threads
- develop very severe or migraine headaches
- have yellowing of the skin or whites of the eyes. These may be signs of liver problems
- have had a stroke or heart attack
- become HIV positive or your partner becomes HIV positive
- have severe vaginal bleeding or bleeding that lasts a long time or concerns you

To learn more, talk about Mirena with your HCP and see the FDA-approved Full Prescribing Information found on <https://www.mirena-us.com/pi>, or call 1-866-647-3646.

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ONE LESS THING TO DO EVERY DAY

If you are looking for a low-maintenance birth control that doesn't require a daily routine, consider Mirena[®].

With Mirena, you'll have to check the threads once a month on your own.



Learn more at [Mirena.com](https://www.Mirena.com)



Scan the QR code with your phone's camera to visit [Mirena.com](https://www.Mirena.com)

If you have any questions about Mirena[®] (levonorgestrel-releasing intrauterine system) 52 mg, you should ask your healthcare provider. You should also learn about other birth control methods, and choose the one that is right for you.



For additional Important Safety Information, please see throughout brochure. Please see [Important Facts](#) on pages 6-9 and the Full Prescribing Information [here](#).

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