

Carefully read the package information leaflet



Mirena is a hormonal intrauterine contraceptive (IUS) in the form of a T-shaped plastic body which is adapted to the uterine cavity. The hormone is released from a capsule that is attached on the vertical part of the T-body. The T-body itself is made of a tissue-friendly plastic and is provided with two threads to enable easy removal from the uterus.

*Active substance (released from the capsule):
levonorgestrel, 52 mg.*

Other: polydimethylsiloxane.

Levonorgestrel is a progestin used in many other contraceptives. With the device in position inside the uterus, it is released at a rate of 15 micrograms/24 hrs for six years.

Mirena's high degree of reliability is attributable to several different factors:

- The progestin affects growth of the endometrial mucous membrane. The membrane becomes thinner and infertile.
- The device also creates a non-beneficial environment for sperm in the uterus and Fallopian tubes. Sperm movement is inhibited and conception is prevented.
- Mirena thickens the cervical mucous, inhibiting sperm movement.
- Although ovulation may sometimes be affected, the overall effect on the body's hormone balance is limited.

Indications

Contraception for up to six years, heavy menstruation without physiologic cause, and protection against mucous membrane growth in women on estrogen therapy for menopause for up to five years.

Contraindications

Genital infections, pathological uterine changes, undiagnosed changes in menstrual cycle, uterine deformities, acute liver disease or tumour.

Note

Pregnancy and genital infection must be excluded before insertion of the device.

Expulsion

Expulsion of the Mirena IUS from the uterus may occasionally go unnoticed by the user. Partial or full expulsion may become noticeable in the form of increased menstrual flow. If you suspect that the device has fallen out, consult your doctor or midwife. Unless the device is properly in place, you will not be protected against unwanted pregnancy.

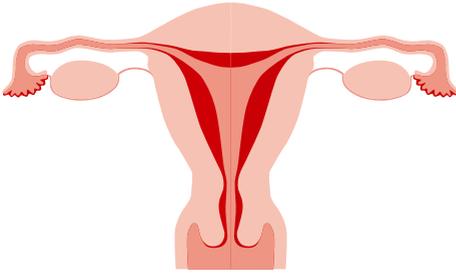
Perforation

Perforation of the wall of the uterus is very rare and occurs primarily in conjunction with insertion. If the uterus is perforated, the device will have to be removed.

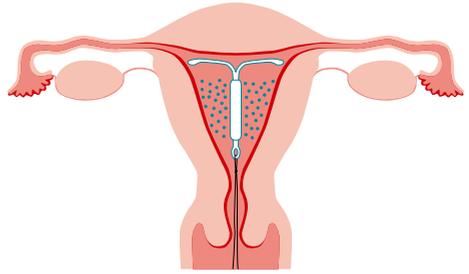
Diabetes

The hormone dose released by the device, although small, may affect your tolerance to glucose. If you are suffering from diabetes, your blood sugar level should be checked regularly.





Uterus without IUS



Uterus with Mirena in place

Changes in the menstrual cycle

Use of the Mirena will cause changes in your normal menstrual cycle. During the first three months, breakthrough bleeding is very common. Although bleeding may be restricted to the occasional spot of blood, copious flows may sometimes be experienced.

Women with abnormally heavy menstrual flows before insertion of the device usually experience many days of spotting for the first four to six months.

The hormone gradually released by the device sets up a local reaction in the uterus, which causes the mucous membrane to enter a state of rest. This, in turn, reduces the flow of menstrual blood and in some women suppresses bleeding altogether. In spite of this, your ovaries and hormone balance remain unaffected.

If you do not have a period for 6–8 weeks, consult your family planning advice center for a pregnancy check-up. If the result is negative, you can safely continue using your Mirena unless other symptoms suggest you may be pregnant.

If after 3–6 months you experience copious irregular bleeding, it is advisable to ask at the family planning advice centre to establish the cause and, if necessary, to recommend some other method of contraception.

Pregnancy

The risk of becoming pregnant with a Mirena in place is very small. If you should become pregnant nevertheless, consult your doctor or midwife without delay. (Since pregnancies with a Mirena in place in the uterus are extremely rare, the effects, if any, of the hormone on the fetus are unknown.)

Breastfeeding

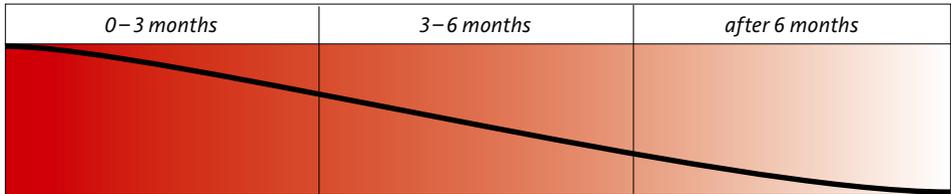
Although Mirena is passed through the milk, the amount is tiny, so it is very unlikely to have any effect on the child.

Other drugs

Advise your doctor/midwife of any drugs you are taking on a regular basis. Your Mirena could be affected by the action of certain drugs.

A bleeding calendar can be good to fill in to see how your bleeding changes. Download the app MinSpiral from the Appstore or Google play. In the app, you fill in a digital diary and report your bleeding during the first three months. Then you get a prediction about your future bleeding profile the next six months. The app also reminds you when it's time to change your spiral. The login code to the app is 6666.

Changes in bleeding pattern



Check-ups

Sometimes you will be asked to attend for a check-up about three months after insertion of your IUS. The number and frequency of your check-ups should be decided in consultation with your doctor or midwife.

Usage

A Mirena IUD can be used by almost all women desiring a safe, convenient means of protecting themselves against undesired pregnancies.

Mirena is inserted inside the uterus within seven days of the start of your period. You may change your IUD or switch to Mirena from some other reliable form of contraception at any time during the menstrual cycle. Your Mirena should be changed after six years if you use it as a contraceptive and after five years for other indications.

Mirena gives you full contraceptive protection as soon as it is inserted.

A Mirena can be removed whenever you wish.

However, you should remember that unless you switch to some other reliable contraceptive you will risk pregnancy as soon as it is removed.

Side-effects

As with any medical treatment, side effects may occur. Due to the low dose and local release, side effects are usually mild and transient. With Mirena, the risk of side effects is greatest during the first months after the insertion. Examples of very common side effects are: abdominal and pelvic pain, headache, vulvovaginitis (inflammation of the external genitals or vagina), bleeding disorders (usually disappear within 3-6 months), and vaginal discharge.

A few women can also feel the device in the form of menstrual-like pain. Few women withdrawal Mirena due to hormonal side effects, as they are usually transient.

Rare side-effects include decreased libido, hair growth, sweating, loss of hair and greasy hair.

There is also a slight risk that you will develop ovarian cysts, although these will normally disappear with time.

Contact your family planning advice centre:

- if you develop a medical problem.
- if you suspect that your IUS is incorrectly inserted.
- if you suspect that you are pregnant.
- if you suffer persistent abdominal pain, temperature, abnormal discharge, migraine or severe headache, high blood pressure or jaundice.

- if your bleeding pattern starts to change – the flow becomes copious or lasts much longer, if you start having period pains, or if bleeding stops altogether.

Miscellaneous

The use of sanitary towels is recommended. If you use tampons, be careful not to pull out your IUS as you remove a tampon.

To ascertain whether your Mirena is still in position, insert a finger in your vagina and make sure you can still feel the threads extending through your cervix.

If you cannot feel the threads, contact your family planning advice centre for a check-up.

Mirena®, intrauterine device, levonorgestrel 20 µg / 24 hours

Indication: Contraception for up to six years. Idiopathic menorrhagia and protection against endometrial hyperplasia during ongoing substitution treatment with estrogen, for up to five years. **Side effects:** Headache, mood changes, acne and bleeding disorders. The side effects is often mild and disappears after a few months of use. **Warnings / Precautions:** Contact a doctor / midwife if you have any of the following conditions or if any of the following conditions occur for the first time when you use Mirena: very severe headache, focal migraines with asymmetric visual loss, jaundice, hypertension, stroke or myocardial infarction. In case of diagnosis of breast cancer, withdrawal of Mirena should be considered. Women who are considering taking Mirena should be informed of signs and symptoms as well as the risk of ectopic pregnancy. Some women who use hormonal contraceptives have reported depression or mood swings. In case of mood swings, contact a midwife or doctor. Read the package information leaflet carefully.

Bayer AB, Box 606, 169 26 Solna, 08 - 580 223 00 www.pharma.bayer.se

