



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 20 micrograms/24 hrs for at least five 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, heavy menstruation without physiologic cause, and protection against mucous membrane growth in women on estrogen therapy for menopause.

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.

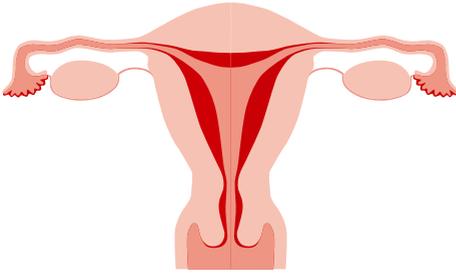
Perforation

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.

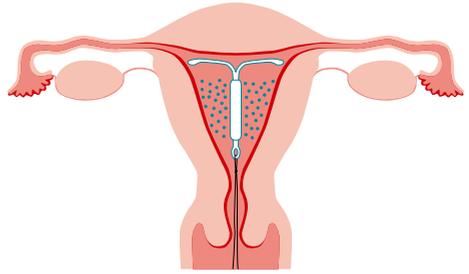
Diabetes

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 centre 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 foetus are unknown.)

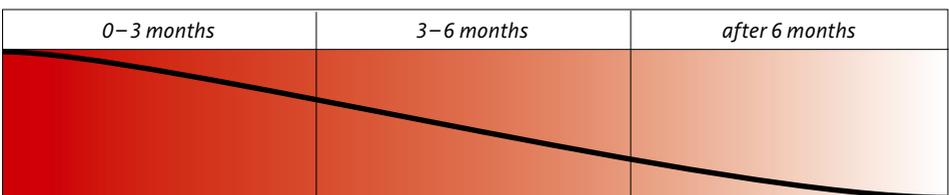
Breastfeeding

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.

Changes in bleeding pattern



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. Idiopathic menorrhagia. Protection against endometrial hyperplasia during ongoing substitution treatment with estrogen. **Side effects:** Headache, mood changes, acne and bleeding disorders. The trouble is often mild and disappears after a few months of use. **Warnings / Precautions:** Mirena should be used with caution or removed after consultation with a specialist if any of the following conditions exist or occur for the first time: 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. Before prescribing please read the product summary on www.Fass.se Anticonceptive agent G02BA03. Rx. F. For more info and prices, see www.fass.se SPC 2018-03-28

Date/Datum _____

Contact/
Kontaktperson _____

Tel _____

Appointments/Återbesök

Bring this card with you whenever you attend for a check-up.

