

B359/07

Package leaflet: information for the user

Mirena, IUD 20 microgram/24 hours
levonorgestrel

Read carefully the entire package leaflet before you take this medicine use because there is important information in for you.

- Keep this leaflet. Maybe you need it later again ..
- you still have questions? Then contact your doctor or pharmacist.
- Do not give this medicine to others , because it is onlyprescribed to you . Itcan can harmful are for others, even if they have the same symptoms as you.
- If you experience any of the side effects listed in section 4 listed? Or experience you a side effect that is not in this leaflet listed? Then contact your doctor or pharmacist.

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1. What is Mirena and what for is this medicine used?

Mirena is an 'intra-uterine device' (IUD), also known as 'coil', that after the insertion every day a small amount of the hormone levonorgestrel releases in the uterus. Because Mirena T-shaped is, remains the IUD well in the uterus positioned. In the vertical part of the white T-shape is a rod that levonorgestrel contains. At the bottom of the T-shape there is an eyelet where two brown-colored removal threads are attached to.

What is Mirena used for?

Mirena can for various reasons be prescribed:

- to prevent pregnancy (contraceptive) (forup to 8 8 year)
- to women who use estrogen hormone therapy in connection with menopausal symptoms, to (excessive) growth of the endometrium prevent to go (for a maximum of 3 years)
- to women who suffer from heavy menstrual bleeding blood loss fora maximum of 8 8 year, as long as your symptoms of severe menstrual bleeding do not return).

How does Mirena work?

Just like the pill contains Mirena a hormone of which the effect on the endometrium (the endometrium) to compare is with that of progesterone (a hormone that by the own body is produced). Levonorgestrel, the hormone in Mirena, is continuously administered and ensures that the endometrium in the endometrium in resting phase enters so that it no longer responds to on estrogens (female hormones that in the ovaries are produced). As a result the endometrium is not anymore built up and the bleedings are stopped much lighter and also less painful.

In the beginning releases Mirena in the uterus per 24 hours an amount of 20 micrograms (= 0.02 mg)

levonorgestrel off. This decreases gradually to what off. The Mirena IUD can maximum 8 years in the uterus remain in place if you use Mirena as contraceptive use. If you use Mirena use for the treatment of heavy menstrual bleeding can Mirena, as long as your symptoms of heavy menstrual bleeding have not returned, maximum 8 year in the uterus remain in place. If you use Mirena for menopausal symptoms use, in combination with estrogen tablets, -patches or -gel, must the IUD after 3 years are replaced. There is namely not yet investigated if Mirena for this method of use longer than 3 years can remain sit.

Mirena as contraceptive (agent that ensures that you do not become pregnant)The contraceptive effect of Mirena is based based on the following effects:

The mucus that is in the cervical canal is becomes 'thicker', making it sperm cells more difficult to pass through can.

Through the release of the hormone levonorgestrel in the uterus can sperm cells here not normally move and function. This reduces the chance on a fertilization.

The endometrium (this is the 'inner lining' of the uterus) is not or barely developed.

As a result can, if there still a fertilization occurs, a fertilized egg not implant .. presence of a one foreign object in the uterus (the Mirena IUD) can an egg that possibly is fertilized not implant ..

some women is becomes the ovulation (ovulation) suppressed. If there is no egg released, fertilization cannot occur fertilization As.

of consequence from this multiple action of Mirena prevents pregnancy and will the blood loss during your menstruation gradually decrease , generally in the general in about three months, significantly reduce.

Mirena for menopausal symptoms

In women in the fertile age is during the natural menstrual cycle - under influence of endogenous estrogenic and progestogenic hormones - the endometrium built up and also again shed (the menstruation).

In women in the menopause stop the menstruations eventually stop and produces the body less hormones .Less estrogen hormone can menopausal symptoms (such as 'hot flashes') cause. A woman with menopausal symptoms can estrogens use to these symptoms counteract to go.

By the use of estrogen hormone is there also again endometrium built up, but if a woman does not anymore menstruate, is the mucosa not more rejected.

Because a thick layer endometrium a increased risk of cancer of the endometrium (endometrial cancer) can cause, must the endometrium regularly be broken down. This can by - in addition to an estrogen hormone - also still a progestogen hormone to use during a number of days per (cycle). An alternative option to prevent excessive growth of the endometrium to, is the growth of the endometrium to suppress. This is the case with Mirena, as a result of the action of the progestogenic hormone levonorgestrel in the IUD.

Children and adolescents to 18 years

Mirena is not intended for use in girls who have not menstruated.

2. When may you this medicine not use or must you extra careful with be?

General remarks

Before Mirena is placed can be ,will will your doctor y a number questions ask about your personal medical history and that of your immediate family members.

Although Mirena very effective is for prevention of unwanted pregnancy, can this still occur. Approximately 2 out of 1000 women in whom Mirena is correctly placed, become pregnant in the first year.

In this leaflet are different situations described in which Mirena must be removed or in which the reliability of Mirena reduced can be. In those situations must you either no sexual intercourse (sex) have or an additional contraceptive without hormones use, such as a condom or another barrier method . Do not use the temperature method or periodic abstinence . abstinence. These methods can be unreliable be, because Mirena the monthly changes of the body temperature and the cervical mucus affects.

Just like other contraceptives with hormones protects Mirena not against infection with the HIV-virus (AIDS) or other sexually transmitted diseases.

When may you this medicine not use?

In the below mentioned situations you must not use Mirena not use. If one of these situations applies to you, application is, must you this to your doctor tell before you use Mirena are going to use. It is possible that your doctor in this case a different contraceptive (without hormones) recommends.

- You are pregnant or might be pregnant could be
- You have a malignant condition that before the growth dependent is on progestogen hormones, such as certain forms of breast cancer
- You have acute or recurrent inflammations in the small pelvis (in the lower abdomen), or you have that had
- You have an inflammation of the cervix (cervicitis)
- You have an inflammation of the genital organs or a STD (sexually transmitted disease)
- You have an inflammation of the endometrium after a delivery (endometritis postpartum)
- You have in the past three months a abortion undergo after which there a infection has occurred
- You have a condition that your immunity prolonged (chronic) reduces or that can worsen due to bacteria in the bloodstream (for example a disorder of the heart valves or a congenital heart defect)
- In you is located the mucous membrane of the cervix itself also in places outside the cervix (cervical dysplasia)
- You have a malignant condition of the uterus or the cervix, or it is suspected that you have this
- You have abnormal bleeding from the vagina of which the cause not known is
- You have a whether or not congenital malformation of the uterus
- You have 'fibroids' in the uterus (myomas) that deform the uterine cavity deform
- You have an acute liver disease or a liver tumor
- You are allergic to one of the substances in this medicine. These substances can you find in section 6 of this leaflet.

When should you be extra careful with this this medicine?

Contact your doctor or pharmacist before you use this medicine.

If you use Mirena simultaneously with a hormone in connection bandage with menopausal symptoms, must you also consider the information in the leaflet of this hormone ..

your doctor if if one of the following conditions applies to you or develops or worsens after Mirena has been inserted in you ::

- loss of vision vision to one side or other symptoms that a sign can be of a stroke (temporary blockage of the blood supply of the brain)
- exceptional severe headache
- sudden increase of your blood pressure
- serious vascular disorders such as a stroke or heart attack.

Mirena is not the first choice for women who have menopause already behind them have and whose the uterus has shrunk (advanced uterine atrophy).

Mirena in smoking

In the general should women who a contraceptive use that hormones contains, should stop smoking . This advice applies also to the use of Mirena.

Mirena and endometriosis

Endometriosis is a condition where the uterine lining (the endometrium) is also on places outside the uterus is located (for example in the intestines). If you this condition have, can you use Mirena use, but your doctor will you probably regularly return have come for check-up. The symptoms will generally become less .If the condition during the use of the Mirena IUD however worsens, it may be necessary in some cases to remove the IUD to remove.

Diabetes

Levonorgestrel, the hormone in Mirena, may - theoretical - the need for glucose change. It can therefore for women who diabetes (diabetes mellitus) have necessary be the glucose levels carefully to check. Usually it is not necessary to adjust diabetes medications to be adjusted.

Menstrual pattern

As a result of the hormone in Mirena will your menstrual pattern will change. Mirena brings the endometrium into a resting phase, a condition that is comparable to that during a period of breastfeeding. Because it several months can take until this new balance is reached, can during these first months after the placement sometimes irregular bleeding occur. Usually it involves spotting bleeding (spotting). The amount of bleeding varies from woman to woman, but decreases usually gradually. During the first month of the use can the bleeding regularly occur, causing it to seem as if the menstruation several weeks persists. After passage of time will the bleeding less become and less frequently occur; after three to six months takes this decreases to a few days blood loss per month. In a small number of women can it occur there is immediately after placement no bleeding anymore is.

Does your menstruation 6 weeks or longer absent after the start of your previous menstruation, tell this then to your doctor. There is nothing to worry about, but to exclude a pregnancy out to rule out can your doctor still decide a pregnancy test to do.

If you use Mirena use in connection with menopausal symptoms and still menstruate, will the monthly blood loss during the first year of use decrease and will the bleeding eventually cease.

Irregular bleeding may the symptoms of a malignant condition of the uterus mask. In case of abnormal bleeding you should therefore contact your doctor. Medical doctor.

Medical examination

Before Mirena is inserted it is possible that your doctor first a number of examinations on you performs, such as a smear of the cervix (Pap-smear), examination of the breasts, examination for infections including STDs, and a pregnancy test. Also will there become examined what the position of your uterus is and how large it is.

Mirena is not suitable for use as emergency contraception (postcoital contraception).

Inflammations in the small pelvis (lower in the abdomen)

Each Mirena IUD is sterile packaged and is sterile as long as the packaging closed remains. During the insertion protects the insertion tube the Mirena against contamination with bacteria or other micro-organisms.

From copper-containing IUDs is known that they an increased risk pose of a infection in the pelvic region. This risk is in the first month after the insertion the highest; afterwards decreases the risk decreases.

The risk of infections is higher when u of your partner multiple sexual partners has or if you not yet children have. Inflammations in the small pelvis must direct treated be. A inflammation in the small pelvis can the fertility affect and the chance of an ectopic pregnancy increase.

In very rare cases can shortly after the insertion of an IUD a serious infection or sepsis (very serious infection, which a fatal outcome can have) occur.

Mirena must be removed in case of repeated infections in the small pelvis or or inflammations of the inner lining of the uterus, or if a acute infection very severe is or does not improve within a few days with the treatment.

Contact immediately your doctor if you experience suffer from persistent pain in the lower abdomen, fever, pain during sex or abnormal bleeding. If you shortly after the insertion severe pain or fever develop, this may indicate that you have a serious infection has that immediately treated must be.

Expulsion of the IUD

In rare cases can the contractions of the muscles of the uterus during menstruation the IUD of are place or out the uterus push. The chance of this is greater if you overweight are at the moment that the IUD in you is placed, or if you suffer from (have had) from heavy menstruations. If the IUD no longer on its place sits, then works it possibly not as intended

and then the chance of pregnancy increased. If the IUD is expelled, you are not more protected against pregnancy.

The possible symptoms of expulsion are pain and abnormal bleeding, but Mirena can also come out without that you notice it .. Mirena usually the blood loss during menstruation reduces ,can more blood loss blood loss at menstruation a indication be that the Mirena out the uterus is come.

It is recommended to with your finger to check if the threads are present are, for example during the showering. See also section 3 "How to use this medicine - - Where must you pay attention during the use of Mirena?" If you signs have that indicate that Mirena out your uterus has come or if you threads cannot feel ,must you use another contraceptive method (such as condoms)and must you contact u contact record with your healthcare provider.

Perforation

Perforation or penetration of the uterine wall can occur, usually during the insertion, although the sometimes only later noticed is. A Mirena that outside the uterine cavity is come to sit does not protect well against pregnancy and must must as quickly as possible be removed. There may be a surgery required .The risk of perforation is increased in women who breastfeeding give, and in women who have given birth in the 36 weeks before the placement and may be increased in in women in whom the uterus is tilted backward (uterus in retroversion-flexion). If you suspect that in you a perforation has occurred, ask then immediately advice from a doctor. Inform that that in you a Mirena has been placed, especially when this doctor not the one is who inserted the IUD has placed.

Possible signs and symptoms of perforation may be:

- severe pain (resembling on menstrual cramps) or more pain than expected
- severe vaginal bleeding (after the insertion)
- pain or vaginal bleeding that longer than a few weeks persists
- sudden changes in your menstrual pattern
- pain during sex
- you cannot no longer the threads of the Mirena feel (see section 3 "How do you use this medicine ? -What should you pay attention to during the use of Mirena?" of Mirena?")

Breast cancer

In women who a combination pill (contraceptive pill with an estrogen and a progestogen hormone) use, is slightly more often breast cancer determined. It is however not known whether it is caused by the use of the pill. It can for example also be that there more breast cancer is detected in women who use a combination pill ,because they are more often by their doctor examined . The risk. The chance on the getting of breast cancer becomes gradually smaller after stopping with a combination pill . Probably. risk of diagnosing on the determine of breast cancer not increased with use of Mirena, a contraceptive method with only a progestogen hormone.

Women under 50 years who still no menopause have had, have no increased risk of breast cancer from Mirena.

The risk of breast cancer is indeed increased in women who have menopause already had experienced and who hormone replacement therapy use in relation to menopausal symptoms in the form of tablets or patches. This risk is higher when the hormone

replacement therapy contains both a progestogen and estrogen hormone, than when the therapy only contains an estrogen hormone. It is important to also consider taking with the information in the leaflet of the hormone replacement therapy.

It is important to regularly check your breasts. If you feel a lump, should you contact your doctor. Ectopic pregnancy

The pregnancy

The chance that you become pregnant during the use of Mirena is very small. But if you become pregnant during the use of Mirena, it is a risk that the embryo is outside the uterus located (ectopic pregnancy) relatively increased. In women in whom the Mirena is correctly placed, the number of ectopic pregnancies is approximately 1 per 1000 women per year. This is less than in women who do not use contraception at all (approximately 3 to 5 per 1000 women per year). Women who have already had an ectopic pregnancy, an operation in the pelvis, inflammation in the small pelvis, or have experienced an increased risk of an ectopic pregnancy. An ectopic pregnancy is a serious condition for which immediate medical assistance is needed. The following symptoms could indicate that you have an ectopic pregnancy:

You menstruate no longer and then get persistent bleeding and/or pain

You have vague or precisely severe pain in your lower abdomen

You have normal pregnancy symptoms, but you have also bleeding and are dizzy.

In this case, direct contact with your doctor.

Dizziness

Some women feel dizzy after the insertion of Mirena. This is a normal reaction of the body. Your doctor will let you rest after Mirena is inserted.

Enlarged follicles in the ovaries

Because the protective effect of Mirena against pregnancy is mainly local (in the uterus), many women in the fertile age usually have a normal cycle with an ovulation. Sometimes enlarged follicles can arise. Usually, these cause no symptoms, but some can cause pain in the pelvis or pain during sex. Generally, enlarged follicles disappear on their own again.

Psychological disorders

Some women who use hormonal contraceptives including Mirena, have reported depression or low mood. Depression can be severe and can sometimes lead to suicidal thoughts. If you experience mood swings and symptoms of depression, then as quickly as possible contact your doctor for further medical advice.

Can tampons or menstrual cups be used?

The use of sanitary pads is recommended. If you use tampons or menstrual cups, you must carefully replace them, so that you do not pull the threads of Mirena. Do you think your Mirena might have pulled (see in the list above for possible signs)? Then you must use a contraceptive such as a condom (barrier method). And you must contact your doctor.

Do you still use other medications?

Because Mirena primarily a local effect has, it is not likely that the use of other medications during the use of Mirena the risk of pregnancy increases. It is however recommended to your doctor or pharmacist to inform if you besides Mirena also other medications use, you that recently have done or if you you this maybe soon goes do. That applies also for medications where you no prescription for needed have.

Pregnancy, breastfeeding and fertility

Pregnancy

You may not use Mirena not use if you are pregnant or think that you are pregnant .

If you during the use of Mirena pregnant becomes, must you immediately to your healthcare provider go to have Mirena removed . The removal can remove miscarriage one miscarriage cause. But if Mirena remains in place during the pregnancy, is not only the risk of a miscarriage greater, but also the risk that your delivery too early starts. If Mirena cannot removed be ,consult then with your healthcare provider about the benefits benefits in risks of continuation of the pregnancy. If the pregnancy is continued, you will be during your pregnancy closely monitored carefully .. U must immediately contact contact with your doctor if you experience suffer from abdominal cramps, pain in your abdomen or fever.

Mirena contains a hormone called levonorgestrel .There have been some reports of effects on the genital organs of female babies who were uterus were exposed to IUDs with levonorgestrel.

Breastfeeding

Mirena can be used during breastfeeding. The daily dose of the hormone in Mirena and the amount in your blood are lower than with oral contraceptives. There are very small amounts of levonorgestrel found in the breast milk (0.1% of the dose is transferred to the infant).

Fertility

After the removal of Mirena returns the normal fertility returns.

Are you pregnant, do you think you pregnant to be, do you want to become pregnant or are you breastfeeding ? Then contact your doctor or pharmacist before you use this medicine . medicine used.

Driving ability and the use of machines

It is not known if Mirena driving ability and the ability to operate machines affects . Mirena.

. Mirena barium sulfate

At the T-shaped part of Mirena is barium sulfate added. This way can Mirena if necessary with X-ray equipment in the body visible become made to to check if the IUD still properly in its place is.

3. How do you use this medicine ?Use

this medicine always exactly as such as your doctor or pharmacist you that has told. Are you unsure about the correct use? Then contact your doctor or pharmacist.

How long can Mirena use?

Mirena is by your doctor in the uterus inserted and is there, depending on the reason why the IUD is used, for 3, 5 or 8 years effective.

When you use Mirena to prevent pregnancy, the IUD is 8 for 8. Used you Mirena for this reason? Then must you Mirena at its latest after 8 years have removed or replaced.

When you use Mirena used for heavy menstrual bleeding, is the IUD 5 years effective. Are you using Mirena for this reason? Then must you have Mirena replaced or removed when your symptoms of severe menstrual bleeding return, or in any case after 8 8 ..

you use Mirena use because because u a estrogen hormone used for menopausal symptoms, is the IUD 3 years effective. Do you use Mirena for this reason? Then must you replace Mirena after are last after 3 years have removed or replaced.

When should Mirena be inserted?

Start with the use of Mirena

Before Mirena is inserted, must be sure that you are not pregnant .

You can Mirena the best within 7 days after the start of your menstruation have inserted. When Mirena on these days is inserted, works Mirena immediately and prevents it that you become pregnant .

If you have Mirena not within 7 days after the start of your menstruation can have inserted, or if your menstruation irregular is, can Mirena on any other day be inserted.

In this case you must not since your last menstruation have sex have had without contraception and must you before the insertion a negative pregnancy test have.

Also can Mirena in this case pregnancy not immediately on reliable manner prevent.

Therefore must you, during the first 7 days after Mirena is inserted, a barrier method for contraception use (such as condoms) or no vaginal sex have.

Mirena is not suitable for use as emergency contraceptive (postcoital contraceptive).

Starting with the use of Mirena after the delivery

Mirena can after the delivery be inserted as soon as the uterus has the normal size has, but not earlier than 6 weeks after the delivery (see section 2 'When should you be extra careful are with this medicine? – Perforation').

See also 'Starting with the use of Mirena' above for what you still more must know about the time of insertion.

Start with the use of Mirena after an abortion

Mirena can immediately after an abortion be inserted if the pregnancy less than 3 months has lasted, provided that there are no genital infections . Mirena works then immediately.

Mirena

Mirena replace

Mirena can at any time of your menstrual cycle be replaced by a new Mirena. Mirena works immediately.

Switching from another contraceptive method contraceptive method (such as combined hormonal contraceptives, implant)

Mirena can directly be inserted if reasonably certain is that you are not pregnant bent. If it more than 7 days ago is that your menstruation started, you must for the next 7 7 refrain abstain of vaginal sex or additional contraception use.

Continuation of contraception after the removal of Mirena

If you do not want to become pregnant, may Mirena not be removed after the seventh day of your menstrual cycle (monthly menstruation), except if you from ten at least seven days before the removal of the IUD another contraceptive contraceptive for example condoms)used . If you irregularly menstruate or or not menstruates, must you from seven days before the removal additional contraception use, and this continue use until your menstruation occurs again. A new Mirena can also directly after removal be inserted, there is then no extra protection needed. If you not the same method want to continue using, ask then your doctor for advice about other reliable contraceptive methods.

How is Mirena placed?

Mirena must be placed by a healthcare provider who has experience with the insertion of Mirena. Before Mirena is inserted in you placed, performed your doctor first a internal gynecological examination. The placement itself takes normally speaking only a few minutes in begins just like a internal examination that you perhaps already once have undergone. Because it insertion sterile must happen, become the vagina and the cervix disinfected. With a so-called tenaculum is the uterus in the correct position held after which the Mirena is inserted. How better you can relax , the less you feel of it . In consultation with the doctor can you a local anesthetic anesthesia get or can you from beforehand certain painkillers take.

After placement of this IUD will your doctor you a reminder card give for the follow-up checks. Take this card to each appointment with you.

When the insertion of Mirena is difficult has occurred or when you serious pain or bleeding during or after the insertion has had, will your doctor by means of a physical examination or via a ultrasound a perforation exclude.

After Mirena in you is inserted, will your doctor you ask after 4 to 12 weeks back to come for check-up and afterwards at least one time per year. Your doctor will decide how often and which type checks necessary are in your case. Take the reminder card that you received from your doctor have received with you at each appointment. If you symptoms have, must you contact call with your doctor.

What must you pay attention to during the use of Mirena?

At the end of the Mirena are two thin threads attached that after the insertion by your doctor to the correct length are cut. These threads make the for you possible yourself to check if Mirena still in its place is. Insert a finger into the vagina until to the cervix: if you there the thin threads can feel, Mirena is in place. Do not pull the threads, because this can the Mirena out of place! When the strings are no longer palpable, they may have moved up into the cervical canal cervical canal of can the Mirena possibly be displaced. It is also possible that the Mirena is outside the uterus located or completely is expelled (expulsion), or that this in or through the wall of the uterus is penetrated (perforation). Consult in this case your doctor and care that you no sex have or that you a barrier method (such as

condoms) use. He/she will then with help of for example ultrasound examination determine where the Mirena is exactly located.

Important

If Mirena is no longer in the correct position is located, then must the IUD removed be and by a new be replaced.

To remove Mirena to remove, does not in general require only carefully on the threads to be pulled. Let this always by your doctor do. Never pull yourself on the threads.

In which cases should you your doctor inform if you use Mirena use?

In the following cases it is advisable to contact your take with your doctor:

- if you think that you are pregnant when
- persistent pain in the lower abdomen ,fever or unusual vaginal discharge
- if you - or your partner - pain has during the intercourse
- if you can plastic part (the T-shape) of Mirena can feel
- if you threads no longer can feel
- with heavy or prolonged bleeding.

Inform your doctor that in you a Mirena is placed, especially when this doctor not the one is who the IUD has placed.

4. Possible side effects

Like any medicine can also this medicine side effects have. Not everyone gets with it to deal.

In the first months after the insertion of Mirena can abdomen- or back complaints occur. Usually disappear these complaints quickly.

In women who a IUD as contraceptive use, occur more often infections of the genital organs than in other women .. the risk of infertility or an ectopic pregnancy pregnancy larger than normal. In use of the Mirena IUD, this risk is lower than with regular, so-called copper-containing IUDs (see also 'Inflammations in the small pelvis'). With Mirena-use are also cases of breast cancer reported.

As a result of the active substance (levonorgestrel) will the menstrual pattern change. In the first few months occurs there more irregular bleeding occurs, afterwards decreases the menstrual bleeding significantly and can this even after passage of time completely stay away.

If you use Mirena use in connection with menopausal symptoms and still menstruate, will it monthly blood loss during the first year of use decrease and will the bleeding eventually cease.

Below are possible side effects reported of Mirena in use as contraceptive or in the treatment of heavy menstrual bleeding.

The possible side effects when Mirena is used to (excessive) growth of the endometrium to prevent in women who use an estrogen hormone in connection with with menopausal symptoms occur even frequently occur, unless otherwise indicated:

Very frequently occurring side effects: may occur in more than 1 in 10 users:

- Headache
- Abdominal pain/ pain in the small pelvis (lower in the abdomen)
- Changes in the menstruation, including more or less blood loss, spotting, irregular menstruations (oligomenorrhea) or the absence of menstruations (amenorrhea)
- Inflammation of the labia or the vagina* (vulvovaginitis)
- Vaginal discharge.*

Often common side effects: may occur in 1 in 10 users:

- Depressed mood/depression
- Nervousness
- Reduced libido (interest in sex)
- Migraine
- Dizziness
- Nausea
- Acne
- Excessive body hair (hirsutism)
- Back pain**
- Benign cysts (with fluid filled cavities) in the ovaries
- Painful menstruation (dysmenorrhea)
- Sensitive breasts
- Painful breasts
- Expulsion of the IUD (complete or partial)
- Weight gain.

Sometimes occurring side effects: may occur in 1 in 100 users:

- Bloating feeling
- Hair loss (alopecia)
- Itching (pruritus)
- Rash (eczema)
- Yellow-brown pigmentation spots on the skin (chloasma)
- Pigmentation spots (skin hyperpigmentation)
- Perforation of the uterus
- Inflammation in the lower abdomen (internal female genital organs above the cervix)
- Inflammation of the endometrium (endometritis)
- Inflammation of the cervix (cervicitis/pap-smear normal, class II)
- Fluid retention (edema).

Rare side effects side effects: occur in 1 in 1000 users users:

- Allergic reactions, including skin rash, hives (urticaria) and sudden swelling in the skin and mucous membranes (e.g. throat or tongue), breathing difficulties and/of itching and skin rash, often as allergic reaction (angio-edema)
- Increase in the blood pressure.

* In clinical studies whereby the protective effect on the endometrium is investigated:
"Common".

** In clinical studies whereby the protective effect on the endometrium is investigated:
"Very common".

The threads can during sex possibly be felt by your partner. If you

become pregnant during the use of Mirena, it is possible that the pregnancy ectopic is (see section 2, 'Ectopic pregnancy').

In rare cases can there perforation of the uterus occur; the IUD penetrates then into or through the wall of the uterus.

Cases of sepsis (very serious infection, which can have a fatal outcome) have been reported after n/a the insertion of IUDs.

There are cases of breast cancer reported.

The following possible side effects have been reported in connection with the insertion or remove of Mirena:

Pain during the insertion/removal

Bleeding during the insertion/removal.

During the insertion or removal of Mirena occurs in very rare cases a reaction that resembles fainting: dizziness, black spots before the eyes, pallor, sweating, nausea or vomiting. This reaction is harmless and resolves within a few minutes spontaneously. If you have epilepsy, can the insertion or removal of Mirena a seizure cause.

Reporting side effects If you experience side effects, contact your doctor or pharmacist. This applies also to side effects that are not in this leaflet. You can report side effects also via the Dutch Side effects Lareb Center, website www.lareb.nl.

By reporting side effects to report, you help us to gain information to obtain about the safety of this medicine.

5. How do you store this medicine? Keep out of

sight and reach of children. Keep out of sight and reach this medicine no special storage conditions.

Mirena is (in the undamaged inner packaging) stable until the expiry date. You find it on the label after 'Insertion must take place before'. There is a month and a year. The last day of that month is the latest extreme expiry date. Mirena must before this date be inserted. If the Mirena IUD once is placed, can it 3 years in the uterus remain if you use it in relation with menopausal symptoms used, 5 years in severe menstrual bleeding (or up to maximum 8 years as long as your symptoms of severe menstrual bleeding still not return) of 8 years if you use the IUD as contraceptive method.

Do not flush medications down the sink or the wc and throw them not in the trash. Ask your pharmacist what to do with medications you should do not use anymore. If you medicines on the correct way disposed are they in a correct way destroyed and enter they not into the environment end up.

6. Contents of the packaging and other information

Which substances are in this medicine?

The active ingredient in this medicine is levonorgestrel. A Mirena contains 52 mg levonorgestrel.

The other substances in this medicine are polydimethylsiloxane elastomer, polydimethylsiloxane Silastic Medical Tubing, polyethylene with barium sulfate (in the T-shaped part), polyethylene with iron oxide colorant (E172) (in the removal thread).

How does Mirena look and what is in a package?

Each package contains one Mirena. The IUD (IUD) is sterile packaged in a hermetically sealed plastic packaging with around it a elongated box.

Holder of the license for the in the trade bringing and manufacturer

Registration holder/repacker

BModesto B.V.

Minervaweg 2

8239 DL Lelystad

Manufacturer

Bayer Oy

Pansiontie 47

20210 Turku

Finland

In the register registered under:

RVG 125012/16681 – Mirena, IUD 20 microgram/24 hours. Country of origin: Bulgaria

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1033/05

INFORMATION FOR THE MEDICAL PROFESSIONAL: INSERTION INSTRUCTIONS

Mirena, IUD 20 microgram/24 hour

Mirena must by a doctor or midwife aseptically be inserted.

Mirena is with an insertion system (inserter) delivered in a sterile package. This may only be opened directly before the insertion is opened. Do not (re. Mirena is sterilize. Mirena is intended for single use. Do not use if the inner packaging is damaged or opened . Do not reinsert after the expiry date expiry date (month, year), which is stated on the label . In the.

of Mirena a reminder card for the patient is included the patient included. Fill this reminder card in and give this after the insertion to the patient ..

for insertion Examination

Research the patient to contra-indications for insertion of Mirena and a pregnancy to exclude (see the Summary of the Product Characteristics Product characteristics, section 4.3 and section 4.4 under 'Medical examination/consultation').

Insert a speculum, visualize the cervix and disinfect the portio and the vagina thoroughly.

Let yourself if necessary be assisted by an assistant(e).

Hook the anterior lip of the portio on with a tenaculum of a other forceps to stabilize the uterus to stabilize. If the uterus is in retroversion position, you better hook the posterior lip . To stretch the cervical canal to stretch tea stretch can you carefully on the forceps pull. The forceps must in its place remain and during the insertion procedure must carefully traction be exerted on the cervix.

Insert a probe through the cervical canal into the fundus to determine the uterine length to determine, to establish the direction of the uterine cavity to determine and to any potential intra-uterine abnormalities to detect (e.g... septum or submucosal myomas) ora previously placed IUD that is not removed is. If the passage difficult proceeds must be considered to cervical canal to dilate. If dilation of the cervix required is, can painkillers and/or one paracervical block be applied.

Insertion

1. Open the sterile packaging completely (figure 1). Proceed sterile to work and use sterile gloves.

2. Push the slider as far as possible forward in the direction of the arrow to load Mirena into the inserter to insert Mirena in the inserter load (figurefigure 2).

IMPORTANT! Push the slider not down because Mirena then too early could be released . After releasecan Mirena can Mirena not again be loaded.

3. Hold the slider in Figure 3 the farthest position with thumb and index finger and place the upper edge of the marking ring at the level that corresponds with the sounded uterine length (figure 3).

4. slider in the While you farthest Figure 4 position holds, brings you the inserter into the cervix upwards until the marking ring approximately 1.5-2.0 cm from the portio removed is (figure 4); this to the horizontal arms of Mirena sufficient space to give to to unfold.

IMPORTANT! Do not force the inserter not. Dilate as necessary the cervical canal.

5. While you the Figure 5 inserter still hold, pull you the slider towards the mark to horizontal arms of Mirena to unfold (figure 5). Wait 5-10 seconds until the horizontal arms are fully opened ..

6. the inserter carefully towards the fundus until the the fundus to the ring against the portio comes. The Mirena must now against the fundus sit (figure 6).

7. Hold the inserter in its place and Figure 7 disconnect Mirena by slider completely down to slide (figure7). While the slider constantly down is being moved held, pull the inserter carefully outward .. the threads at approximately 2-3 cm distance from the cervix ..

suspect suspects that Mirena not in the correct position is, you must check the position verify (e.g.. ultrasonically). Remove Mirena if it itself not in the correct position is located. A Mirena that removed is, may not be reinserted be inserted.

Removal/replacement

See for removal/replacement the Summary of the Product Characteristics of Mirena.

Mirena is removed by gently a forceps carefully on the threads to pull (figure 8). If the threads are not visible and Mirena is intra- uterinelocated ,a narrow forceps can be used become used to remove Mirena to remove.

For this it may dilation of the cervical canal be necessary.

After removal you can immediately a new Mirena insert.

After the removal of Mirena must the IUD be checked to ensure whether it is intact and whether it is completely intact is removed. See the paragraph below for more information.

Important!

The use of excessive force/sharp instruments during the removal of Mirena can a breakage of the IUD cause. After the removal of Mirena must the IUD therefore be checked to be ensure after to check if it is intact and if it is in its entirety is removed. In case of difficult removal it has been reported in some cases that the hormone cylinder (medication core and membrane) over the horizontal arms slid, so that the arms in the cylinder were hidden . Asuch situation requires no none further intervene if Mirena further complete is. The thickenings at the end of the arms normally prevent speaking that the cylinder completely releases of the T-shape.

After the removal of Mirena can there also immediately a new IUD be inserted; in this case is no additional contraception needed.

In the register registered under:

RVG 125012//16681 – Mirena, IUD 20 microgram/24 hour. Country of origin: Bulgaria

This information for the medical profession is for the last approved in September 2024