

Package leaflet: information for the user

Kyleena 19.5 mg, intrauterine delivery system

levonorgestrel

Read the entire leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do you have any questions? Contact your doctor or midwife who places (hormonal) coils.
- Do not pass this medicine on to others, as it is prescribed only for you.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or midwife who places (hormonal) coils.

Contents of this leaflet

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

Kyleena is a T-shaped delivery system for use in the uterus. It is also known as a hormonal coil. Kyleena prevents you from becoming pregnant (it is a contraceptive). It prevents pregnancy for up to 5 years. Kyleena contains a hormone called levonorgestrel.

How does Kyleena work?

A doctor or midwife who places (hormonal) coils inserts Kyleena into your uterus. Once the hormonal coil is in place, it continuously releases a small amount of hormone.

Kyleena ensures that sperm cells do not come into contact with your egg cell. This prevents you from becoming pregnant. Kyleena works by:

- thickening the mucus in your cervix. This prevents sperm cells from passing through your cervix.
- keeping the tissue inside your uterus thin.

2. When should you not use this medicine or be extra careful with it?

Good to know about Kyleena

Your doctor or midwife who places (hormonal) coils must be sure that this contraceptive method is suitable for you. Therefore, your doctor or midwife who places (hormonal) coils will first ask a few questions about your health. Only then will you be prescribed Kyleena.

Kyleena prevents you from becoming pregnant (contraceptive). There is no contraceptive that always ensures you do not become pregnant. Each year, approximately 2 to 3 out of 1000 users still become pregnant.

Kyleena does not protect you against HIV or other sexually transmitted diseases (STDs). HIV is the virus that can lead to AIDS.

Kyleena is not an emergency contraceptive that you can use to prevent pregnancy, like a morning-after pill. Have you had unprotected sex shortly before Kyleena was placed? Then you may become pregnant.

When should you not use this medicine?

- You are pregnant. See the section 'Pregnancy, breastfeeding, and fertility' below.
- You have an inflammation of your uterus, fallopian tubes, or ovaries (pelvic inflammatory disease). Or you have had such an inflammation more than once.
- You have a condition that increases the risk of pelvic infections. For example, sexually transmitted diseases (STDs) or diseases that impair your body's ability to fight infections. Such as a severe stage of an HIV infection.
- You have an inflammation in your vagina or cervix.
- You have given birth to a baby, had an abortion, or miscarriage in the past 3 months and subsequently had an inflammation of your uterus.
- The result of your last smear test (cervical examination) was not normal.
- You have cancer in your uterus or cervix. Or your doctor or midwife who places (hormonal) coils thinks you might have this.
- You have a tumor that needs progestogen hormones to grow. Such as breast cancer.
- You are losing blood from your vagina and you do not know the cause.
- Your cervix or uterus does not have a normal shape. For example, due to a fibroid in your uterus (non-malignant tumor).
- You have a disease or tumor in your liver.
- You are allergic to levonorgestrel or any of the ingredients in this medicine. You can find these ingredients in section 6 of this leaflet.

Does any of the above situations apply to you? Then do not use Kyleena. Are you unsure? Contact your doctor or midwife who places (hormonal) coils.

When should you be extra careful with this medicine?

Contact your doctor or midwife who places (hormonal) coils before using Kyleena if you:

- have diabetes. Usually, you do not need to adjust your diabetes medication when using Kyleena. But your doctor or midwife who places (hormonal) coils may need to check this.
- have epilepsy. You may have a seizure during the placement or removal of Kyleena.
- have ever had an ectopic pregnancy (pregnancy outside the uterus).
- have migraines that affect your vision. Such as suddenly seeing less well with one eye. Or if you have migraines that cause other problems (migraine with aura). Or if you have other severe headaches and do not know the cause.
- have jaundice. Your skin, nails, and whites of your eyes turn yellow.
- have high blood pressure.
- have ever had a stroke or heart attack.

Does any of the above situations apply to you? Or are you unsure? Contact your doctor or midwife who places (hormonal) coils before having Kyleena placed.

Contact your doctor or midwife who places (hormonal) coils immediately if you are using Kyleena and you:

- have signs that indicate pregnancy. Or if your pregnancy test is positive. See the section 'Pregnancy, breastfeeding and fertility' below.
- shows signs that indicate a pregnancy, but also has pain or bleeding from your vagina or feels dizzy. You may have an ectopic pregnancy. See section 4 under 'Ectopic pregnancy'.
- stomach pain, fever, abnormal discharge from your vagina, or pain during sex. You may have an infection. You should receive medication quickly. See section 4 under 'Pelvic infection'.
- pain during sex. You may have a small fluid-filled sac in your ovary (cyst). See section 4 under 'Ovarian cysts'.
- severe pain or heavy bleeding, or if you can no longer feel the threads of Kyleena. You may have a perforation. See section 4 under 'Perforation'.

Do you have any of the complaints above? Contact your doctor or midwife who places (hormonal) coils immediately.

Also contact your doctor or midwife who places (hormonal) coils about Kyleena if you:

- have a migraine or very severe headache for the first time.
- notice that your skin, nails, and whites of your eyes turn yellow. These are symptoms of jaundice.
- notice that you have high blood pressure.
- have had a stroke or heart attack.

Your doctor or midwife who places (hormonal) coils will decide if you can continue to use Kyleena safely.

Pay attention to symptoms that indicate Kyleena may no longer be in place.

Symptoms that Kyleena may no longer be in place can include:

- you can no longer feel the threads of Kyleena with your finger in your vagina. See section 3 under 'How to check if Kyleena is in place?'.
- you or your partner feels the lower plastic part of Kyleena. See section 3 under 'How to check if Kyleena is in place?'.
- you suddenly have changes in your menstruation. For example, you initially stop menstruating with Kyleena, but then suddenly start again.

These symptoms may mean that Kyleena has come out of your uterus. See section 4 under 'Kyleena comes out of your uterus'. It may also mean that you have a perforation. See section 4 under 'Perforation'.

Do you have any complaints that Kyleena is no longer in place? Contact your doctor or midwife who places (hormonal) coils immediately. Use a condom or diaphragm during sex until your doctor or midwife who places (hormonal) coils has checked whether the hormonal coil is still in place.

Your partner may feel the threads of Kyleena during sex. This does not mean that the hormonal coil is no longer in place. Is your partner bothered by the threads? Then your doctor or midwife who places (hormonal) coils can do a few things to ensure that your partner no longer feels the threads.

Menstrual products

Are you menstruating? Then it is best to use sanitary pads. Do you use tampons or a menstrual cup? Then change them carefully. Otherwise, you might accidentally pull on the threads of Kyleena. Do you think you might have dislodged Kyleena? Then use a condom or diaphragm during sex until you visit your doctor or midwife who places (hormonal) coils. See above for possible complaints.

Breast cancer

Women who use the pill (contraception) have a slightly increased risk of breast cancer. This returns to the age-appropriate baseline risk within 10 years after stopping the pill. Some scientific studies have suggested a slightly increased risk of breast cancer with the use of a levonorgestrel IUS like Kyleena, while other studies have not suggested an increased risk. Talk to your doctor if you have any concerns.

Problems with your mental health

Some women experience depression or a depressed mood when using hormonal methods to prevent pregnancy (hormonal contraceptives). Like Kyleena. See section 4 under 'Problems with your mental health' for more information.

Children and adolescents up to 18 years

Girls who have not yet started menstruating should not use Kyleena.

Are you using any other medications?

Are you using any other medications besides Kyleena, have you done so recently, or are you planning to do so soon? Then tell your doctor or midwife who places (hormonal) coils.

Pregnancy, breastfeeding, and fertility

Pregnancy

Are you pregnant? Then you should not have Kyleena placed.

Are you no longer menstruating while using Kyleena?

Some women do not menstruate while using Kyleena. Are you no longer menstruating? Then it is probably due to Kyleena. You can read more about this in section 4 under 'Irregular or occasional bleeding due to menstruation'.

Have you not menstruated for 6 weeks? Then you can take a pregnancy test. Does the test indicate that you are not pregnant? Then you do not need to take it again.

Do you have signs of pregnancy?

Do you have signs of pregnancy? For example, you no longer have your period, feel nauseous, and have tender breasts? Then you should:

1. take a pregnancy test
2. contact your doctor or midwife who places (hormonal) coils for examination.

Have you become pregnant?

Have you become pregnant while using Kyleena? Then make an appointment with your doctor or midwife who places (hormonal) coils immediately. Your doctor will remove Kyleena from your uterus.

You may have a miscarriage if Kyleena is removed from your uterus. But if Kyleena remains in your uterus during your pregnancy, you have a higher chance of:

- a miscarriage
- your baby being born prematurely

Contact your doctor or midwife who places (hormonal) coils about the benefits and risks of a pregnancy with Kyleena still in your uterus. Your doctor or midwife who places (hormonal) coils will monitor you closely. Contact your doctor or midwife who places (hormonal) coils immediately if you experience:

- cramps in your abdomen
- pain in your abdomen
- fever

Kyleena contains a hormone called levonorgestrel. Ask your doctor or midwife who places (hormonal) coils about the potential effects of this hormone on the developing baby in your uterus. There have been a few reports that coils with levonorgestrel affect the sex organs of female babies in the womb.

Ectopic pregnancy

The chance of becoming pregnant with Kyleena is very small. If you do become pregnant while using Kyleena, there is a greater chance that the fertilized egg is not in your uterus, but in your fallopian tube or abdominal cavity. This is called an ectopic pregnancy. Such a pregnancy is serious. You need immediate medical help. After an ectopic pregnancy, it may be more difficult to become pregnant again. See section 4 under 'Ectopic pregnancy'.

Breastfeeding

You can use Kyleena while breastfeeding. A small amount of hormone enters the breast milk. The chance that Kyleena affects the quality or quantity of your breast milk is small. The chance that it affects the growth and development of the baby who is breastfeeding is also small.

Fertility

Do you want to become pregnant? Then contact your doctor or midwife who places (hormonal) coils to have Kyleena removed from your uterus.

Kyleena does not affect your fertility after it has been removed from your uterus.

Driving ability and the use of machines

As far as is known, Kyleena does not affect how well you can drive or operate machines.

3. How do you use this medicine?

Starting the use of Kyleena

Before Kyleena is placed in you, you must be sure that you are not pregnant.

It is best to have Kyleena placed within 7 days after the start of your period. Is the hormonal coil placed on these days? Then it works immediately and ensures that you do not become pregnant.

Can't you have Kyleena placed within 7 days after the start of your period? Or do you have irregular periods? Then the hormonal coil can be placed on any other day. You must not have had sex without means to ensure you do not become pregnant (contraception) since your last period. You must also have a negative pregnancy test before placement. Kyleena cannot immediately reliably ensure that you do not become pregnant. Use a barrier method for 7 days after placing Kyleena to prevent pregnancy. For example, condoms. Or do not have vaginal sex.

Kyleena is not a method you can use in an emergency to prevent pregnancy (emergency contraceptive). Like a morning-after pill.

Starting the use of Kyleena after childbirth

Kyleena can be placed after childbirth as soon as your uterus has returned to its normal size. This should not be earlier than 6 weeks after delivery. See section 4 under 'Perforation'.

See also 'Starting the use of Kyleena' above for more information on the timing of placement.

Starting the use of Kyleena after an abortion

Did your pregnancy last less than 3 months? And do you have no infections in your reproductive organs? Then Kyleena can be placed immediately after your abortion. It works immediately.

Starting the use of a new Kyleena when the Kyleena you currently have needs to be replaced

Kyleena can be replaced with a new Kyleena at any time during your monthly cycle. It works immediately.

Switching from another method to prevent pregnancy to Kyleena (such as a combination of hormonal contraceptives or an implant)

Are you quite sure that you are not pregnant? Then Kyleena can be inserted immediately.

Did your period start more than 7 days ago? Then you should not have vaginal sex for the next 7 days or use additional contraceptive methods.

What happens during the insertion of Kyleena?

Examination before insertion

Your doctor or midwife who inserts (hormonal) coils may perform several examinations before inserting Kyleena. For example:

- a smear test of your cervix
- breast examination
- other examinations if necessary. For example, for sexually transmitted infections (STIs).

Inserting Kyleena

Your doctor or midwife who inserts (hormonal) coils will first check the size of your uterus. They will also determine the exact position of your uterus in your abdomen (pelvic examination).

Your doctor or midwife who inserts (hormonal) coils will insert a speculum into your vagina. Then, they will clean your cervix with an antiseptic solution. Sometimes, they may apply local anesthesia to your cervix. After that, they will insert Kyleena into your uterus using a thin, flexible plastic tube (insertion tube).

The insertion of Kyleena can be uncomfortable. Some women may feel dizzy or faint. You may also experience pain or slight vaginal bleeding. This is common.

After insertion, your doctor or midwife who inserts (hormonal) coils will give you a card. This is the patient reminder card. You can write on the card when your next Kyleena check-up is. Bring this card to every appointment.

Check-up after insertion

You should have your Kyleena checked 4 to 6 weeks after insertion by a doctor or midwife who inserts (hormonal) coils. They will decide how often you need to return for check-ups. You should return for a check-up at least once a year. Bring the reminder card to every appointment.

How do you check if Kyleena is in place?

You check this by gently inserting a finger into your vagina. You should be able to feel the threads at the top of your vagina, near your cervix. Your cervix is the entrance to your uterus. Be careful not to pull on the threads, as this could accidentally dislodge Kyleena from your uterus.

Can't you feel the threads? Have your doctor or midwife who places (hormonal) coils check if Kyleena is still in place. You should not have sex until you have seen your doctor or midwife who places (hormonal) coils. Unless you use a condom or diaphragm.

Do you feel the lower plastic part of Kyleena? Or can your partner feel it? Then Kyleena is not properly in place. Contact your doctor or midwife who places (hormonal) coils immediately. You should not have sex until you have seen your doctor or midwife who places (hormonal) coils. Unless you use a condom or diaphragm.

The removal of Kyleena

Kyleena works for a maximum of 5 years. After 5 years, the hormonal coil must be removed from your uterus. You can also have it removed at any time before the 5 years are up. Your doctor or midwife who places (hormonal) coils will remove the hormonal coil. After that, you can become pregnant again.

It can be a bit uncomfortable to have Kyleena removed from your uterus. Some women become dizzy or faint during or immediately after the removal of Kyleena. You may also feel some pain or bleed from your vagina. This is common.

Continue using methods to prevent pregnancy after the removal of Kyleena

Do you not want to become pregnant after the removal of Kyleena? Then consider the following:

Kyleena is best removed within 7 days after the start of your period. Is Kyleena removed outside of your period? Then use a condom or diaphragm during sex for 7 days before removal.

Do you have irregular periods or no periods at all? Then use a condom or diaphragm during sex for 7 days before the removal of Kyleena. Having irregular periods means that the number of days between your periods is not always the same.

Immediately after Kyleena is removed from your uterus, a new Kyleena can also be placed. Then no extra protection is needed. Do you not want to continue using the same method? Ask your doctor or midwife who places (hormonal) coils for advice on other reliable methods to prevent pregnancy.

4. Possible side effects

Like any medicine, this medicine can have side effects. Not everyone experiences them.

Serious side effects

Below are some serious side effects. Are you experiencing serious side effects? Then contact your doctor or midwife who places (hormonal) coils immediately:

stomach pain, fever, abnormal discharge or abnormal bleeding from your vagina, or pain during sex. You may have an infection of your uterus, fallopian tubes, or ovaries. See below under 'Pelvic infection'.

severe pain after placement such as menstrual pain, more pain than you expected, or heavy bleeding from your vagina. Or pain or bleeding that lasts longer than a few weeks, sudden changes in your monthly cycle, pain during sex, or you no longer feel the threads of Kyleena. These may be symptoms of a perforation. See below under 'Perforation'.

you first stop having periods, but then have vaginal bleeding that does not stop. Or you have severe pain in your lower abdomen that does not go away. These may be symptoms of an ectopic pregnancy. See below under 'Ectopic pregnancy'.

you have a fluctuating mood and symptoms of depression. See below under 'Problems with your mental health'.

allergic reactions. Such as skin rash, rash on the skin with pink bumps and severe itching (hives), or swollen tongue, lips, face, or throat. These complaints are very rare.

Do you think one of the situations above applies to you? Then contact your doctor or midwife who places (hormone) coils immediately.

Other side effects

Below are other side effects you may experience. The side effects at the top of the list are the most common. The side effects at the bottom of the list are the least common.

Very common: occur in more than 1 in 10 users

headache

abdominal pain or pelvic pain

pimples (acne) or oily skin

changes in your monthly cycle. For example:

- o more or less blood loss than normal
- o bleeding or slight bleeding (spotting) while you are not menstruating

- o you are irregular or only occasionally menstruate
- o you no longer menstruate at all

You can read more about this in the section 'Irregular or occasional bleeding due to menstruation'.

small fluid-filled sac in your ovary (ovarian cyst). You can read more about this in the section 'Ovarian Cysts'.

inflammation of your labia and vagina (vulvovaginitis).

Common: occur in less than 1 in 10 users

reduced interest in sex (decreased libido)

migraine

feeling dizzy

feeling nauseous

hair loss

pain during menstruation

painful or tender breasts

Kyleena expels itself from your uterus (completely or partially). You can read more about this in the section 'Kyleena expels from your uterus'.

vaginal discharge

weight gain

Sometimes: occur in less than 1 in 100 users

more hair on your body.

Description of some possible side effects:

Ectopic pregnancy

Symptoms of an ectopic pregnancy can include:

you stopped having periods, but then you have vaginal bleeding that does not stop

you have severe pain in your lower abdomen that does not go away

you have normal signs of pregnancy. For example, feeling nauseous or having tender breasts. But you also have vaginal bleeding and feel dizzy.

your pregnancy test is positive.

Are you experiencing this? Contact your doctor or midwife who places (hormonal) coils immediately.

The chance of becoming pregnant with Kyleena is very small. If you do become pregnant, there is a higher chance that the fertilized egg is not in your uterus, but in your fallopian tube or abdominal cavity. This is called an ectopic pregnancy. Each year, about 2 in 1,000 women using Kyleena experience an ectopic pregnancy. Such a pregnancy is serious. You will need immediate medical attention. You may need to undergo surgery.

Some women have a higher risk of an ectopic pregnancy. These are women who:

have previously had an ectopic pregnancy

have had surgery on the fallopian tubes

have had a pelvic infection.

Irregular or occasional bleeding due to menstruation

There is a high chance that your monthly cycle will change due to Kyleena. For example:

- you experience some bleeding while you are not menstruating. This is called spotting.
- your periods become less regular. The number of days between your periods is not always the same.
- your periods are shorter or longer.
- you lose less or more blood than normal during your period.
- you stop having periods.

Sometimes you only experience changes in the first few months after placement. For example:

- Bleeding when you are not menstruating or spotting is most common in the first 3 to 6 months.
- Some women initially have heavier periods than normal.

You may lose slightly less blood each month and have shorter periods. Some women eventually stop having periods altogether.

Are you no longer menstruating at all? That is usually normal. It usually does not mean that you are pregnant or going through menopause. Normally, the tissue inside your uterus thickens every month. This is to prepare your uterus for pregnancy. Then this tissue thins again during your menstruation. Kyleena reduces the thickening of the tissue inside your uterus. As a result, you may no longer menstruate. The amount of hormones in your body usually remains normal.

Is Kyleena being removed from your uterus? Then you usually get your normal menstruation again. If this does not happen, contact your doctor or midwife who places (hormonal) coils.

Pelvic infection

Kyleena is free from bacteria, viruses, and fungi (sterile). The insertion device is also sterile. However, you can get a pelvic infection during or within 3 weeks after the placement of Kyleena. For example, an infection in the tissue inside your uterus, fallopian tubes, or ovaries. This occurs in less than 1 in 10 users.

You may experience:

- abdominal pain
- fever
- abnormal vaginal discharge
- pain during sex.

The risk of getting a pelvic infection is higher if:

- you have a sexually transmitted disease (STD)
- you or your partner have multiple sexual partners
- you have previously had a pelvic infection.

Do you have a pelvic infection? Then it is important to see a doctor immediately. A pelvic infection can cause:

- fertility problems later. You may have more difficulty becoming pregnant.
- an ectopic pregnancy if you become pregnant (ectopic pregnancy).

a severe infection or sepsis. This is very rare. It occurs shortly after the placement of Kyleena. Sepsis means you are very ill due to an infection. Sepsis can be fatal if not treated.

You must have Kyleena removed if the pelvic infection:

- recurs multiple times
- is very severe
- does not go away with treatment.

Kyleena comes out of your uterus

Kyleena can be expelled from your uterus or fall out of your uterus. This is due to contractions of the muscles in your uterus when you have your period. This occurs in less than 1 in 10 users. This is especially likely if you:

- are overweight when Kyleena is inserted
- have previously experienced very heavy periods

Is Kyleena no longer in place? Then it may not work properly anymore. You have a higher chance of becoming pregnant. If Kyleena comes out of your uterus, it no longer protects you against pregnancy.

Is Kyleena no longer in place? Or has it come out of your uterus? Then you may have pain or vaginal bleeding that is different from normal. Kyleena can also come out of your uterus without you noticing.

Usually, Kyleena reduces bleeding during your period.

The longer you use Kyleena, the less blood you lose during your period. If you suddenly start losing more blood again during your period, this may mean that Kyleena has come out of your uterus. See section 3 'How to check if Kyleena is in place?' to check if it is in place, and what to do if you think the hormonal coil is no longer in place.

Perforation

Kyleena may be pushed into or through the wall of your uterus. This is called perforation. A perforation usually occurs during the insertion of Kyleena. A perforation does not always cause pain. Therefore, you may not notice it until later. If your hormonal coil is no longer in place due to perforation, it no longer protects against pregnancy. Your doctor must remove your hormonal coil from your uterus as soon as possible. Sometimes surgery is necessary.

A perforation occurs in less than 1 in 1,000 users. The risk of perforation is higher for you (occurs in less than 1 in 100 users) if:

- you are breastfeeding during the insertion of Kyleena
- you have given birth in the last 9 months before the insertion of Kyleena.

You may have a perforation if you:

- have severe pain that feels like menstrual pain or more pain than you expected
- have very heavy vaginal bleeding after insertion
- have pain or bleeding that lasts longer than a few weeks
- have sudden changes in your monthly cycle
- pain during sex
- no longer feel the threads of Kyleena.

Do you think you have a perforation? Then contact a doctor or midwife who (hormonal) coils. Tell your doctor or midwife who places (hormonal) coils that Kyleena has been placed in you. Especially if your doctor or midwife who places (hormonal) coils did not place Kyleena themselves.

Ovarian cysts

Sometimes a small fluid-filled sac appears on an ovary when you have Kyleena. Such a sac is called an ovarian cyst.

Symptoms of an ovarian cyst can include:

- pain in your pelvis
- pain or discomfort during sex.

Usually, an ovarian cyst disappears on its own. Sometimes medical help is needed. In rare cases, you may need surgery. Do you think you have an ovarian cyst? Then contact your doctor or midwife who places (hormonal) coils.

Problems with your mental health

Some women who use hormonal methods to prevent pregnancy (including Kyleena) experience depression or a depressed mood.

Depression can be severe. It can sometimes lead to suicidal thoughts. Has your mood changed? And are you experiencing depressive symptoms? Then contact your doctor or midwife who places (hormonal) coils as soon as possible. Depression and depressed mood occur in less than 1 in 100 users of Kyleena.

Reporting side effects

If you experience side effects, contact your doctor or midwife who places (hormonal) coils. This also applies to side effects not listed in this leaflet. You can also report side effects via the Netherlands Pharmacovigilance Centre Lareb, website www.lareb.nl. By reporting side effects, you help us gain more information about the safety of this medicine.

5. How do you store this medicine?

There are no special storage conditions for this medicine.

Keep out of the sight and reach of children.

Do not open the blister pack (the plastic packaging containing Kyleena). Only your doctor or midwife who places (hormonal) coils may do this.

Do not use this medicine after the expiry date. You will find it on the box and the blister pack after EXP. It includes a month and a year. The last day of that month is the expiry date.

6. Contents of the package and other information

What substances are in this medicine?

The active substance in this medicine is levonorgestrel. The hormonal coil contains 19.5 mg of levonorgestrel.

The other substances in this medicine are:

- polydimethylsiloxane elastomer
- silicon dioxide, colloidal anhydrous
- polyethylene
- barium sulfate
- polypropylene
- copper phthalocyanine
- silver.

What does this medicine look like and what is in a package?

Kyleena is a hormonal coil (delivery system for use in the uterus). It is T-shaped and white. The upright part contains a small tube with the hormone levonorgestrel. At the loop at the bottom, there are two blue threads. With these, a doctor or midwife who places (hormonal) coils can remove Kyleena from the uterus. There is also a silver ring on Kyleena, close to the arms from left to right. Your doctor or midwife who places (hormonal) coils can see this ring on an ultrasound during an examination.

Package size:

- 1x1 hormonal coil (delivery system for intrauterine use)
- 5x1 hormonal IUD (intrauterine delivery system)

It is possible that not all pack sizes are marketed.

Marketing authorization holder and manufacturer Authorization holder:

Bayer B.V.
Siriusdreef 36
2132 WT Hoofddorp

For information:

Bayer B.V., P.O. Box 88, 2130 AB Hoofddorp

Manufacturer:

Bayer Oy
Pansiontie 47
20210 Turku
Finland

Registered under number: RVG 118462

This medicine is registered in member states of the European Economic Area under the following names:

- Belgium, Denmark, Germany, Estonia, Finland, France, Ireland, Italy, Iceland, Latvia, Lithuania, Netherlands, Norway, Austria, Poland, Portugal, Slovenia, Spain, Czech Republic, Sweden: Kyleena

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Transtoyou