PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

KYLEENA

Levonorgestrel Intrauterine delivery system 17,5 µg/24 hours
Intrauterine Delivery System (IUS)

Read all of this leaflet carefully before you start using KYLEENA.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- KYLEENA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT KYLEENA CONTAINS:

The active substance is levonorgestrel. Each sterile intrauterine system contains anhydrous and micronised levonorgestrel 19, 5 mg.
The other ingredients are barium sulphate; copper phthalocyanine; polydimethylsiloxane elastomer; polyethylene, polypropylene; silica colloidal anhydrous; silver.

WHAT KYLEENA IS USED FOR:

KYLEENA is a T- shaped intrauterine system (IUS) which after placement in the womb slowly release a small amount of the hormone levonorgestrel. The mechanism of action of KYLEENA is within the womb and only small amounts of the hormone enter the blood.

KYLEENA is used for prevention of pregnancy for up to 5 years.

Only about 2 in 1000 women correctly using KYLEENA become pregnant in the first year. Only about 15 in a 1000 women with correctly placed KYLEENA become pregnant in 5 years.

BEFORE YOU ARE GIVEN KYLEENA:

You should not be given KYLEENA:

- If you are hypersensitive (allergic) to levonorgestrel or any of the other ingredients of KYLEENA
- If you are pregnant
- If currently have pelvic inflammatory disease (infection of the female reproduction organs) or have had this condition multiple times in the past
- If you have conditions associated with increased susceptibility to pelvic infections
- If you have a lower genital tract infection (infection in the vagina or the cervix i.e. neck of the womb) that has not been treated
- If you have infection of the womb after delivery of a baby, an infected abortion or miscarriage during the past 3 months
- If you have cell abnormalities in the cervix
- If you have cancer of the cervix or womb
- If you have tumours which depend on progestogen hormones to grow
- If you have unexplained uterine bleeding
- If you have an abnormality of the cervix or womb including fibroids that distort the cavity of the womb
- If you have an active liver disease or liver tumour.

Tell your doctor or healthcare professional before being given KYLEENA:

If any of the following conditions exists before KYLEENA use or appears for the first time while using KYLEENA, consult a healthcare professional, who will help to decide whether or not it is appropriate to use or continue using KYLEENA:

- migraine, with visual disturbances or other symptoms, which may be signs of a transient cerebral ischaemia (temporary blockage of the blood supply to the brain)
- severe headache
- jaundice (a yellowing of the skin, whites of the eyes, and/or nails)
- blood pressure
- severe disease of arteries such as stroke or heart attack

Tell your healthcare professional if you were born with heart disease (congenital) or you have heart valve disease.

If you have diabetes, there is generally no need to alter the diabetic medication while using KYLEENA, but this may need to be checked by your healthcare professional.

Medical examination/consultation: Examination before insertion may include a cervical smear test (Pap smear), examination of the breasts and other tests, e.g. for infections, including sexually transmitted diseases, as necessary.

Your healthcare professional will do a gynaecological examination to determine the position and size of the womb.

Faintness/seizure: Some women feel dizzy after KYLEENA is inserted or removed. This is a normal physical response. Your healthcare professional will tell you to rest a while after you have had KYLEENA inserted or removed. If you have epilepsy, tell your healthcare professional, because a fit (seizure) can occur during insertion or removal.

Irregular or infrequent bleeding: You may have bleeding and spotting between menstrual periods, especially during the first 3 to 6 months. Sometimes the bleeding is heavier than usual at first.

However, the bleeding usually becomes lighter than usual and may become irregular and/or infrequent. Consult your healthcare professional if the bleeding remains heavier than usual or if the bleeding becomes heavy after it has been light for a while.

Pelvic Infections: The KYLEENA inserter and KYLEENA itself are sterile and have been designed to minimise the risk of infection. Despite this, there is an increased risk of pelvic infections (infections in the lining of the womb or the fallopian tubes) at the time of insertion and during the first 3 weeks after the insertion. Pelvic infection in users of IUS (Intra Uterine System) such as KYLEENA is often related to sexually transmitted diseases.

The risk of infection is increased if you or your partner have multiple sexual partners or have had pelvic infection before. Pelvic infections must be treated promptly. Pelvic infection, such as pelvic inflammatory disease (PID), may have serious consequences, and it may impair fertility and increase the risk of a future extra-uterine pregnancy (pregnancy outside the womb).

Severe infection or sepsis (very severe infection) can occur shortly after KYLEENA insertion. KYLEENA must be removed if there are recurrent pelvic infections or if an acute infection is severe or does not respond to treatment.

Consult your healthcare professional without delay if you have persistent lower abdominal pain, fever, pain in conjunction with sexual intercourse or abnormal bleeding. Severe pain or fever developing shortly after insertion may mean that you have a severe infection which must be treated immediately.

Expulsion: The muscular contractions of the womb during menstruation may sometimes push KYLEENA out of place or expel it, which means it comes out by itself. Possible symptoms are pain and abnormal bleeding. If the KYLEENA is displaced, the effectiveness may be reduced and therefore the risk of pregnancy increased. If KYLEENA is expelled, you are not protected against pregnancy anymore. As KYLEENA typically decreases menstrual flow over time, increase of menstrual flow may be a sign that KYLEENA has been expelled.

Perforation or penetration of the wall of the womb may occur. If it does occur, it most often happens during placement, even though it may not be detected until sometime later.

A KYLEENA that has become lodged outside the cavity of the womb is not effective at preventing pregnancy. You may need surgery to have KYLEENA removed. The risk of perforation is increased in breastfeeding women and in women who had a delivery up to 36 weeks before insertion and may be increased in a woman with the uterus leaning backward (fixed retroverted uterus).

Extrauterine pregnancy: If you become pregnant while using KYLEENA, the risk that the pregnancy could develop outside the womb (have an extrauterine or ectopic pregnancy) is increased. About 2 in 1000 women whom KYLEENA was correctly inserted have an extrauterine pregnancy per year. This rate is lower than in women not using any contraception (about 3 to 5 in a 1000 women per year).

Women who already had an extrauterine pregnancy, surgery of the fallopian tubes or a pelvic infection carry a higher risk for this type of pregnancy. An extrauterine pregnancy is a serious condition which calls for immediate medical attention. The following symptoms could mean that you may have an extrauterine pregnancy and you should see your doctor immediately:

- Your menstrual periods have ceased, and then you start having persistent bleeding or pain
- You have pain in your lower abdomen
- You have normal signs of pregnancy, but you also have bleeding and feel dizzy.

Ovarian cyst (cells that surround a maturing egg in the ovary): Since the contraceptive effect of KYLEENA is mainly due to its local effect in the womb, ovulation (release of the egg) usually continues in fertile women while using KYLEENA. Sometimes an ovarian cyst may develop. In most instances there are no symptoms, although on occasion there may be pelvic pain or pain during intercourse. This cyst may require medical attention or more rarely, surgery, but it usually disappear on its own.

Magnetic Resonance Imaging (MRI): Magnetic resonance testing under most standard conditions may be carried out safely during use of KYLEENA. Your healthcare professional may refer to the KYLEENA healthcare professional information for information about suitable conditions for MRI testing.

Pregnancy and Breastfeeding:
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using KYLEENA.

Pregnancy:
KYLEENA must not be used during an existing or suspected pregnancy. Some women may not have their periods while using KYLEENA. Not having a period is not necessarily a sign of pregnancy. If you do not have your period and have other symptoms of pregnancy (for example nausea, tiredness and breast tenderness) you should see your healthcare professional for an examination and have a pregnancy test.

If you become pregnant with KYLEENA in place, you should have KYLEENA removed as soon as possible. There is a risk of spontaneous miscarriage if KYLEENA is removed during pregnancy. If you leave KYLEENA in place during pregnancy, the risk of having a miscarriage, infection or preterm labour will be increased. Talk with your healthcare professional about the benefits and risk of continuing the pregnancy.

Breastfeeding:
You can use KYLEENA during breastfeeding. Levonorgestrel (the active ingredient in KYLEENA) has been identified in small quantities in the breast milk of breastfeeding women (0,1 % of the dose being transferred to the infant). There appears to be no negative effects on infant growth or development when using KYLEENA six weeks after delivery. Levonorgestrel does not appear to affect the amount or the quality of breast milk.

Consult a healthcare professional or pharmacist before taking any medicine when you are pregnant or breastfeeding.

Fertility:
Your usual level of fertility will return after KYLEENA is removed.

Driving and using machinery:
No known effects.

Using other medicines with KYLEENA:
Please tell your doctor if you are taking other medicines on a regular basis, including complementary or traditional medicines and medicines obtained without a prescription.

The mechanism of action of KYLEENA is mainly local, the intake of other medicines is not believed to increase the risk of pregnancy while using KYLEENA. However, it is advised that you tell your healthcare professional if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

HOW TO USE KYLEENA:
Your doctor will tell you how long your treatment with KYLEENA will last. Do not remove KYLEENA early because you will not be protected from falling pregnant. If you have the impression that the effects of KYLEENA is too strong or too weak, tell your doctor or pharmacist.

When should KYLEENA be inserted:
You can have KYLEENA inserted within seven days from the onset of the menstrual bleeding (your monthly period). KYLEENA can also be inserted immediately after a first trimester abortion provided that there are no genital infections. KYLEENA can be inserted after giving birth only after womb has returned to its normal size after delivery and not earlier than 6 weeks after delivery (see section "Before you use KYLEENA – Perforations). KYLEENA can be replaced by a new system at any time of the cycle.

Additional information on special populations:
Children and adolescents:
The effectiveness and safety of KYLEENA have not been established in children and adolescents under the age of 18 years.

Elderly patients (65 years or older):
KYLEENA is not indicated for use in postmenopausal women.

Patients with impaired liver function:
KYLEENA must not be used in women with active liver disease and/or liver tumour. If you have a liver impairment, tell your healthcare professional (see section "Do not use KYLEENA").

Patients with impaired kidney function:
KYLEENA has not been studied in women with kidney impairment.

How is KYLEENA inserted:
After a gynaecological examination, an instrument, called a speculum, is placed into the vagina and the cervix may be cleansed with an antiseptic solution. KYLEENA is then inserted into the womb using a thin, flexible plastic tube (the insertion tube). Local anaesthesia may be applied to the cervix prior to insertion.

Some women may experience pain and dizziness during or after insertion. If these do not pass within half an hour in the resting position, KYLEENA may not be correctly positioned. Your healthcare professional will examine you to see if KYLEENA needs to be removed or replaced.

You may experience some bleeding and/or pain during or after insertion. After placement of KYLEENA you may receive a patient reminder card from your doctor for follow-up examinations. Bring this with you to every scheduled appointment.

When should I see my healthcare professional?
You should have your KYLEENA checked 4 to 12 weeks after placement and thereafter regularly, at least once a year. If you received a patient reminder card from your doctor bring this with you to every scheduled appointment.
In addition, you should contact your healthcare professional if any of the following occurs:

- You no longer feel the thread in your vagina
- You can feel the lower end of KYLEENA

- You think you may be pregnant
- You have persistent abdominal pain, fever or unusual discharge from the vagina You or your partner feel pain or discomfort during sexual intercourse
- There are sudden changes in your menstrual periods (e.g. if you have little or no menstrual bleeding, and then start having persistent bleeding or pain, or you start bleeding heavily)
- You have other medical problems, such as migraine headache or intense headache that recur, sudden problems with vision, jaundice or high blood pressure
- You experience any of the conditions mentioned in section “Before you use KYLEENA”.

For how long can KYLEENA be used?
KYLEENA is effective for up to five years, after which it has to be removed. If you like, you may have a new KYLEENA inserted when the old one is removed.

What if I want to become pregnant or have KYLEENA removed for another reason?
KYLEENA can be easily removed at any time by your healthcare professional, after which pregnancy is possible. After removal, fertility returns to your usual level.

If pregnancy is not desired, KYLEENA should not be removed after the seventh day of the menstrual cycle (monthly period) unless contraception is covered with other methods (e.g. condoms) for at least 7 days before removal. If you have irregular periods (menses) or no periods, you should use barrier methods of contraception for 7 days before removal until your menstruation reappears. A new KYLEENA can also be placed immediately after removal, in which case no additional protection is needed.

Can I become pregnant after stopping use of KYLEENA?
Yes. After KYLEENA is removed, you may become pregnant.

Can KYLEENA affect my menstrual periods?
Yes. KYLEENA may affect your menstrual cycle. It can change your menstrual periods so that you have spotting (a small amount of bleeding), irregular, shorter or longer periods, lighter or heavier bleeding, or no bleeding at all.

Many women have frequent spotting or light bleeding in addition to their periods for the first 3-6 months after they have KYLEENA inserted. Some women may have heavy or prolonged bleeding during this time. Please inform your healthcare professional, especially if this persists.
Overall, you are likely to have a gradual reduction in the amount and number of the days of bleeding each month.
When the system is removed, periods soon return to normal.

Is it abnormal to have no periods?
No. Not when you are using KYLEENA. The monthly thickening of the lining of the womb may not happen due to the effect of the hormone and therefore there is nothing to come or shed away as menstrual period. It does not necessarily mean that you have reached menopause or are pregnant. Your own hormone levels usually remain normal.

How will I know if I am pregnant?
Pregnancy is unlikely while using KYLEENA, even if you do not have periods. If you have not had a period for six weeks and are concerned, then consider having a pregnancy test. If this is negative, there is no need to carry out another test unless you have other signs of pregnancy, e.g. sickness, tiredness or breast tenderness.

Can KYLEENA cause pain or discomfort?
Some women feel pain (like menstrual cramps) after insertion. You should return to your healthcare professional or clinic if you have severe pain or if the pain continues for more than a few weeks after you have had KYLEENA inserted. You may experience some pain during removal of KYLEENA.

Will KYLEENA interfere with sexual intercourse?
KYLEENA should not interfere with sexual intercourse. If you or your partner feel the IUS during intercourse, intercourse should be avoided until your healthcare professional has checked that the IUS is still in the correct position.

How long should I wait to have sexual intercourse after the insertion?

It is best to wait about 24 hours after having KYLEENA inserted before having sexual intercourse.

Can tampons be used?
Use of sanitary pads is recommended. If tampons are used, you should change them with care so as not to pull the threads of KYLEENA.

What happens if KYLEENA comes out by itself?
It is rare but possible for KYLEENA to come out during your menstrual period without you noticing. An unusual increase in the amount of bleeding during your period could mean that your KYLEENA has been expelled. It is also possible for your KYLEENA to partially expel from your womb (you or your partner may notice this during sexual intercourse).
If KYLEENA is completely or partially expelled, you will not be protected from pregnancy.

How can I tell whether KYLEENA is in place?
You can check yourself if the threads are in place for example after your period. Gently put a finger into your vagina and feel for the threads at the end of your vagina near the opening of your womb (cervix).

Do not pull the threads because you may accidentally pull out KYLEENA. If you cannot feel the threads, this may indicate that an expulsion or perforation has occurred. In this case you should avoid intercourse or use a barrier contraceptive (such as condoms), and consult your healthcare professional.
If you have any further questions on the use of this medicine, ask your doctor.

POSSIBLE SIDE EFFECTS:
KYLEENA can have side effects.
Not all side effects reported for KYLEENA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using this medicine, please consult your doctor, pharmacist or other healthcare professional for advice healthcare.
The following is a list of side effects that have been linked with the use of KYLEENA:

Frequent side effects:
- Headache
- Abdominal/pelvic pain
- Acne/seborrhoea (greasy skin)
- Bleeding changes including increased and decreased menstrual bleeding, spotting, infrequent periods (oligomenorrhoea) and absence of bleeding (amenorrhoea)
- Ovarian cysts
- Vulvovaginitis (inflammation of the external genital organs or vagina)
- Depressed mood/depression
- Migraine
- Nausea (feeling sick)
- Upper genital tract infection
- Painful menstruation (dysmenorrhea)
- Breast pain/discomfort
- Expulsion of KYLEENA (complete and partial)
- Genital discharge.

Less frequent side effects:
- Hirsutism (excessive body hair)
- Uterine perforation*

**The perforation risk is higher (between 1 and 10 in every 1000 patients) in women who are breastfeeding at the time of insertion and when it is inserted up to 36 weeks after delivery.*

Hypersensitivity including rash, urticaria (hives) and angioedema (swelling of face, lips, cheeks, tongue or throat) may occur.
The removal threads may be felt by the partner during intercourse.

If you become pregnant while using KYLEENA, there is a possibility that the pregnancy is outside the womb (see “Before you use KYLEENA – Extrauterine pregnancy”).

For other IUDs cases of sepsis (very severe systemic infections, which may be fatal) have been reported following IUD insertion.

The following possible side effects have been reported in connection with KYLEENA insertion or removal procedure:

Procedural pain, procedural bleeding, insertion-related vasovagal reaction with dizziness or syncope (fainting). The procedure may result in a seizure (fit) in an epileptic patient.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist or other healthcare professional.

STORING AND DISPOSING OF KYLEENA:
Store all medicines out of reach of children.
Store at or below 30 °C.
Do not use KYLEENA after the expiry date which is stated on the package.
Medicines should not be disposed of via wastewater or household waste.
Ask your pharmacist how to dispose of medicines no longer required.
These measures will help to protect the environment.

PRESENTATION OF KYLEENA:
The system, with the accessories, is packed in a thermoformed blister package (tray) and a peelable lid.

IDENTIFICATION OF KYLEENA:
KYLEENA is a T- shaped intrauterine delivery system (IUS) which after insertion releases the hormone levonorgestrel into the womb. The purpose of the T- body is to adjust the system to the shape of the womb. The vertical arm of the white T- body carries a drug reservoir containing levonorgestrel. Two blue coloured removal threads are tied to the loop at the lower end of the vertical arm. In addition, the vertical stem containing a silver ring located close to the horizontal arms, which is visible under ultrasound examination.

KYLEENA can be distinguished from other IUSs by the combination of the visibility of the silver ring on ultrasound and the blue colour of the removal threads.
The T- frame of KYLEENA contains barium sulphate, which makes it visible in X-ray examination.

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