Package leaflet: Information for the user

Exlutena 0,5 mg tablets
Lynestrenol

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor/midwife or pharmacist.
- This medicine has been prescribed for you only. Do not pass it to others. It might harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor/midwife or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Exlutena is and what it is used for

Exlutena is used for prevention of unwanted pregnancy. When Exlutena is taken correctly (without missing tablets), the risk of becoming pregnant is very low.

Exlutena contains a small amount of one type of female sex hormone, the progestogen lynestrenol. For this reason Exlutena is called a minipill. Contrary to combined pills, mini-pills do not contain an estrogen hormone. Exlutena inhibits conception by:
• prevention of the sperm cells from entering the womb by increasing the viscosity of the cervical mucus, thus reducing sperm penetration.
• mostly (in 70% of the women) no ovulation occurs.

In contrast to the combined pill, Exlutena can be used by women who do not tolerate estrogens and by women who give breast-feeding. A disadvantage is that vaginal bleeding may occur at irregular intervals. You also may not have any bleeding at all.

2. What you need to know before you take Exlutena

Do not take Exlutena

Do not take Exlutena if you have or have had any of the conditions listed below. If any of these apply to you, tell your doctor/midwife before starting to use Exlutena. You may get the advise to use a non-hormonal method of birth control.
• If you have a thrombosis. Thrombosis is the formation of a blood clot in a blood vessel [e.g. of the legs (deep venous thrombosis) or the lungs (pulmonary embolism)].
• If you have jaundice (yellowing of the skin) or severe liver disease.
• If you have or have had a tumor that is sensitive to sex steroids, such as certain types of breast cancer.
• If you have any unexplained vaginal bleeding.

• If you are allergic to the active substance or any of the other ingredients of Exlutena.

If any of the above conditions appear for the first time, worsen or recur while using Exlutena, you should contact your doctor/midwife.

Warnings and precautions

In this leaflet, several situations are described where you should stop using Exlutena, or where the reliability of Exlutena may be decreased. In such situations you should not have sex or you should take extra non-hormonal contraceptive precautions, e.g., use a condom or another barrier method. Do not use rhythm or temperature methods. These methods can be unreliable because Exlutena alters the usual changes in temperature and cervical mucus that occur during the menstrual cycle.

Exlutena, like all hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

What do you need to know before using Exlutena?
If Exlutena is used in the presence of any of the conditions listed below, you may need to be kept under close observation. Your doctor/midwife will explain to you what to do. Therefore, if any of these apply to you, tell your doctor/midwife before starting to use Exlutena:
• you have or have had breast cancer;
• you have liver cancer;
• you have had a thrombosis;
• you have diabetes;
• you have had a pregnancy outside the womb (ectopic pregnancy);
• you have or have had an infection or surgery of the fallopian tube;
• you suffer from epilepsy;
• you suffer from tuberculosis;
• you have high blood pressure;
• you have or have had chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face); if so avoid too much exposure to the sun or ultraviolet radiation.

If any of the above conditions appear for the first time, worsen or recur while using Exlutena, you should contact your doctor/midwife.

The Pill and Breast Cancer
Every woman is at risk of breast cancer whether or not she takes oral contraceptives ('the Pill'). Breast cancer has been found slightly more often in women who take the Pill than in women of the same age who do not take the Pill. When women stop taking the Pill, the risk gradually decreases, so that 10 years after stopping the risk is the same as for women who have never taken the Pill. Breast cancer is rare under 40 years of age but the risk increases as the woman gets older. Therefore, the extra number of breast cancers diagnosed is higher if the woman is at a higher age. How long a woman takes the Pill is less important.
In every 10 000 women who take the Pill for up to 5 years but stop taking it by the age of 20, there would be less than 1 extra case of breast cancer found up to 10 years after stopping, in addition to the 4 cases normally diagnosed in this age group. Likewise, in 10 000 women who take the Pill for up to 5 years but stop taking it by the age of 30, there would be 5 extra cases in addition to the 44 cases normally diagnosed. In 10 000 women who take the Pill for up to 5 years but stop taking it by the age of 40, there would be 20 extra cases in addition to the 160 cases normally diagnosed.
Breast cancers found in women who take the Pill, seem less likely to have spread than breast cancers found in women who do not take the Pill. It is not known whether the difference in breast cancer risk is caused by the Pill. It may be that the women were examined more often, so that the breast cancer was noticed earlier.

The Pill and Thrombosis (blood clot)
Thrombosis is the formation of a blood clot, which may block a blood vessel. A thrombosis sometimes occurs in the deep veins of the legs (deep venous thrombosis). If this clot breaks away from the veins where it is formed, it may reach and block the arteries of the lungs, causing a so-called pulmonary embolism. As a result, fatal situations may occur. Deep venous thrombosis is a rare occurrence. It can develop whether or not you are taking the Pill. It can also happen if you become pregnant.
The risk of thrombosis is higher in Pill-users than in non-users. The risk with progestogen-only pills like Exlutena is believed to be lower than in users of Pills that also contain estrogens (combined Pills). If you notice possible signs of a thrombosis, you should see your doctor immediately. (See also '*When should you contact your doctor*?')

Ovarian Cysts
During the use of minipills, small fluid-filled sacs may develop in the ovaries. These are called ovarian cysts. They usually disappear on their own. Sometimes they cause mild abdominal pain. Only rarely, they may lead to more serious problems.

Psychiatric disorders
Some women using hormonal contraceptives including Exlutena have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

Other medicines and Exlutena
Some medicines may stop Exlutena from working properly. These include medicines used for the treatment of epilepsy (e.g., primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate), tuberculosis (e.g., rifampicin) and HIV infections (e.g., ritonavir, nelfinavir), or other infectious diseases (griseofulvin), medical charcoal used for stomach upset and the herbal remedy St. John's wort *(Hypericum perforatum)* primarily used for the treatment of depressive moods. Exlutena may also interfere with the working of other medicines.
Please inform your doctor/midwife or pharmacist if you are taking or have recently taken any other medicines or herbal products, even those not prescribed. Your doctor/midwife can tell you if you need to take additional contraceptive precautions and if so, for how long.

Pregnancy and breast-feeding

Pregnancy
Exlutena must not be used by women who are pregnant, or who think they may be pregnant.

Breast-feeding
Exlutena does not influence the amount or the quality of breast milk. Small amounts (0.14 % of the amount ingested by the mother) of the active substance pass over in breast milk and there are no indications of any risk for the baby. Tell your doctor/midwife if you want to use Exlutena during breast-feeding.

Driving and using machines
There are no observed effects.

Exlutena contains lactose
Exlutena contains lactose. If you do not tolerate certain sugars, contact your doctor/midwife before starting with Exlutena.

When should you contact your doctor?

Regular check-ups
When you are using Exlutena, your doctor/midwife will tell you to return for regular check-ups. In general, the frequency and nature of these check-ups will depend on your personal situation.

Contact your doctor/midwife as soon as possible if:
• you notice possible signs of a thrombosis (e.g. severe pain or swelling in either of your legs, unexplained pains in the chest, breathlessness, an unusual cough, especially if you cough up blood);
• you have a sudden, severe stomach ache or look jaundiced (indicating possible liver problems);
• you feel a lump in your breast;
• you have a sudden or severe pain in the lower part of your belly or the stomach area (possibly indicating an ectopic pregnancy, this is a pregnancy outside the womb);
• you are to be immobilised (for example being confined to bed) or are to have surgery; consult your doctor at least four weeks in advance;
• you have unusual, heavy vaginal bleeding;
• you suspect that you are pregnant.

The situations and symptoms mentioned above are described and explained in more detail elsewhere in this leaflet.

3. How to take Exlutena

When and how to take the tablets?

The Exlutena pack contains 28 tablets. On the back side of the pack, the days of the week are printed on the foil, with arrows printed between them. Each day corresponds with one tablet. Each time you start a new pack of Exlutena, take a tablet in the top row. If you start on a Wednesday, you must take the tablet from the top row marked with WED. Continue to take one tablet a day until the pack is empty, always following the direction indicated by the arrows. By looking at the back of the pack, you can easily check whether you have taken your daily tablet. Take your tablet at about the same time each day. Swallow each tablet whole, with water. You may have some bleeding during the use of Exlutena, but you must continue to take your tablets as normal. When a pack is empty, you must start with a new pack of Exlutena on the next day - thus without interruption and without waiting for a bleed.

Starting your first pack of Exlutena

• *If you have not used any hormonal contraceptive in the past month*
Take the first tablet on the first day of menstrual bleeding. Take a tablet marked with that day of the week. Exlutena will work immediately, it is not necessary to use an additional contraceptive method.
You may also start on days 2-5 of your cycle, but in that case make sure you also use an additional contraceptive method (e.g. condom) for the first 7 days.

• *If you change from a combined oral contraceptive pill (COC), vaginal ring, or transdermal patch*
You can start taking Exlutena on the day after you take the last tablet from your present Pill pack, or on the day of removal of your vaginal ring or patch (this means no tablet-, ring-, or patch-free week). If your present Pill pack also contains inactive tablets you can start Exlutena on the day after taking the last active tablet (if you are not sure which this is, ask your doctor/midwife or pharmacist). If you follow these instructions, it is not necessary to use an additional contraceptive method.

• *If you change from another progestogen-only pill (mini-pill)*
You may stop taking it any day and start taking Exlutena right away. You need not take extra contraceptive precautions.

• *If you change from an injectable or implant or a progestogen-releasing intrauterine device (IUD)*
Start using Exlutena when your next injection is due or on the day that your implant or your IUD is removed.

• *If you just had a baby*
If you have just had a baby, your doctor/midwife may tell you to wait until after your first normal period before you start taking Exlutena. Sometimes it is possible to start sooner. Your doctor/midwife will advise you.

• *If you just had a miscarriage, or an abortion*
Your doctor/midwife will advise you.

If too many Exlutena tablets are taken

There have been no reports of serious harmful effects from taking too many Exlutena tablets at one time. Symptoms that may occur are nausea, vomiting and, in young girls, slight vaginal bleeding.

If you have forgotten to take Exlutena

If you are **less than 3 hours** late in taking a tablet, the reliability of Exlutena is maintained. Take the missed tablet as soon as you remember and take the next tablets at the usual times.

If you are **more than 3hours** late in taking a tablet, the reliability of Exlutena may be reduced. The more consecutive tablets you have missed, the higher the risk that the contraceptive efficacy is decreased. Take the last missed tablet as soon as you remember and take the next tablets at the usual times. Use additional protection (e.g. condom) for the next 7 days of tablet-taking. If you missed one or more tablets in the first week of tablet-intake and had intercourse in the week before missing the tablets, there is a possibility of becoming pregnant. Ask your doctor/midwife for advice.

If you suffer from gastro-intestinal disturbances (e.g., vomiting, severe diarrhoea)

If you have vomited or taken medical charcoal within 3-4 hours after taking your Exlutena tablet or have severe diarrhoea, the active ingredient may not have been completely absorbed. Follow the same advice as for missed tablets.

If you have unexpected bleeding

Vaginal bleeding may occur at irregular intervals during the use of Exlutena. This may be just slight staining or a bleeding, which looks rather like a menstrual bleeding. You may also not have any bleeding at all. The irregular bleedings are not a sign that the contraceptive protection of Exlutena is decreased. In general, you need not take any action; just continue to take Exlutena. If, however, bleeding is heavy or prolonged consult your doctor/midwife.

If you stop taking Exlutena

You can stop taking Exlutena at any time you want. If you stop because you want to get pregnant, it is generally recommended that you wait until you have had a natural period before trying to conceive.
If you have further questions regarding this medicinal product contact your doctor/midwife or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Serious undesirable effects associated with the use of contraceptive Pills are described in the section '*When do you need to take special care with Exlutena?'* Please read this section carefully and consult your doctor/midwife where appropriate.

Other side effects reported by users of Exlutena or of hormonal contraceptives in general are:

Common (more than 1 of 100 users): Irregular bleeding, loss of menstruation, breast tenderness, breast pain, breast secretion, increase in body weight, headache, migraine, nausea, abdominal pain, rash, urticaria, painful blue-red rashes (erythema nodosum), chloasma (brown patches on the skin), fluid retention, depressive mood, mood changes and decreased libido.

Less common (less than 1 of 100 users): Contact lens intolerance, vomiting, diarrhoea, vaginal secretion and breast enlargement.

Rare (less than 1 of 1000 users): Decrease in body weight, hypersensitivity, increased libido.

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

Reporting of side effects
If you get any side effects, talk to your doctor/midwife or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Exlutena

Keep this medicine out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on the carton after Utg.dat. The epiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Exlutena contains

- The active substance is lynestrenol (progestogenic hormone) 0,5 mg.
- The other ingredients are potato starch, amylopectin, lactose monohydrate (circa 43 mg) and magnesium stearate.

What Exlutena looks like and contents of the pack

One blister pack contains 28 white round tablets.
The tablets are coded TT2 on one side and ORGANON* on the reverse. Each carton contains 1 or 3 blister packs.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Merck Sharp & Dohme B.V.
Box 581
2003 PC Haarlem
The Netherlands
Manufacturer
N.V. Organon
PO Box 20

NL-5340 BH Oss
The Netherlands

Further information can be obtained from:
Merck Sharp & Dohme (Sweden) AB
Box 45192
104 30 Stockholm
Tel: 077-570 04 88

This leaflet was last approved in
2021-02-23