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 or your pharmacist.

If any of the side effects get severe, talk to your doctor or your pharmacist. This includes any side effects not listed in this leaflet.

What is in this leaflet
1. What Exluton is and what it is used for
2. What you need to know before you take Exluton
3. How to take Exluton
4. Possible side effects
5. How to store Exluton
6. Additional information

1. What Exluton is and what it is used for

Exluton contains only one female sex hormone, the progestogen lynestrenol. For this reason Exluton is also called a mini-pill. In contrast to combined pills, mini-pills do not contain an oestrogen hormone in addition to the progestogen. The two main ways in which Exluton works are:

- Preventing the sperm cells from entering the uterus.
- Preventing egg cells from maturing (in 70% of the women).

In contrast to the combined pill, Exluton can be used by women who do not tolerate oestrogens and by women who are breastfeeding. A disadvantage of Exluton is that menstrual bleeding may occur at irregular intervals. There is also a chance that no bleeding occurs at all.

Why do you use Exluton?
To prevent pregnancy.
When Exluton is taken correctly (without missing tablets), the chance of pregnancy is very low.

2. What you need to know before you take Exluton

General

This package leaflet describes various situations in which you should stop taking the pill, or in which the pill’s reliability may be reduced. In those situations you should not have sex, or you must use an extra non-hormonal contraceptive. In general, a condom or another barrier method is appropriate. Do not use the rhythm method or temperature method. They can be unreliable, because the pill affects the monthly changes in body temperature and cervical mucus.

The pill, and thus also Exluton, does not protect against HIV infection (AIDS) or against other sexually transmitted diseases.

Do not take Exluton:
Do not use Exluton in the situations listed below. If any of these apply to you, tell your doctor before starting Exluton. Your doctor may advise you to use a non-hormonal method of birth control.
• if you have thrombosis. Thrombosis is the formation of a blood clot which can block a blood vessel, for example in a leg (deep venous thrombosis) or in the lungs (pulmonary embolism).
• if you have or have had jaundice (yellowing of the skin) or severe liver disease, and your liver function is not yet normal.
• if you have or are suspected to have a cancer that is sensitive to sex hormones, such as certain types of breast cancer.
• if you have any unexplained vaginal bleeding.
• if you are allergic (hypersensitive) to lynestrenol or any of the other ingredients of Exluton mentioned in section 6.1.
If any of these situations develop while you are using Exluton, consult your doctor immediately.

Warnings and precautions
Please contact your doctor or pharmacist before using this medicine.
In certain situations, while taking Exluton you may need to be kept under close observation. Your doctor can explain what you should do. Therefore, if any of these situations apply to you, tell your doctor before starting to use Exluton:
• you have or have had breast cancer;
• you have liver cancer;
• you have ever had thrombosis;
• you have diabetes;
• you have ever had a pregnancy outside the uterus (ectopic pregnancy);
• you have or have had an infection of the fallopian tube(s) or have had surgery of the fallopian tube(s);
• you have epilepsy;
• you have high blood pressure;
• you have or have had chloasma (yellowish-brown pigmentation patches on the skin, also called ‘the mask of pregnancy’, particularly on the face); if so, it is advisable to avoid direct exposure to the sun or ultraviolet light.

If any of the above situations occur for the first time, recur or worsen while using Exluton, talk to your doctor.

Breast cancer
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, and 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 with age. Therefore, the number of additional cases of breast cancer is higher among women who use the pill at a higher age. How long a woman is on the pill is less important.

In every 10,000 women who take the pill for 5 years but stop taking it at the age of 20, there would be less than 1 extra case of breast cancer detected 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 5 years but stop taking it at 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 5 years but stop taking it at the age of 40, there would be 20 extra cases of breast cancer in addition to the 160 cases normally diagnosed. The risk of breast cancer in users of mini-pills like Exluton is believed to be similar to the risk in users of the combined pill, but evidence for this is less conclusive.

Breast cancers found in women who take the pill are usually in a less advanced stage than those 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 on the pill are examined more often, so breast cancer is detected earlier.
Thrombosis
Thrombosis is the formation of a blood clot, which can block a blood vessel. Thrombosis sometimes occurs in the deep veins of the lower leg (deep venous thrombosis). If this clot breaks away from the veins where it is formed, it may reach and block an artery in the lungs (pulmonary embolism). This can have a fatal outcome. Deep venous thrombosis is a rare condition. It can develop whether or not you are taking the pill. It can also occur during pregnancy.

The risk of thrombosis is slightly higher in pill-users than in non-users and, in addition, higher in users with a history of symptoms of thrombosis. It is unknown whether this also applies to pills such as Exluton, which only contain a progestogen hormone. In any case, the risk is less than during pregnancy.

If you suddenly have symptoms that could indicate thrombosis, you should contact your doctor immediately (see also ‘When should you contact your doctor while taking Exluton?’).

Ovarian cysts
During the use of all low-dose hormonal contraceptives (like the mini-pill), small fluid-filled sacs may develop in the ovaries. These are called ovarian cysts. They usually disappear on their own, but sometimes they cause abdominal pain. Only rarely can they lead to more serious problems.

Vaginal bleeding
Over the first few months, vaginal bleeding may occur at irregular intervals. This may be just a few drops or heavier bleeding, as in a light menstrual period, for which you need sanitary protection. There is also a chance that you will not have any bleeding at all. This does not mean that there is less protection against pregnancy. In general, you do not have to take action, and you can simply continue taking Exluton. If the bleeding is heavy or prolonged, however, contact your doctor.

When should you contact your doctor?

Regular check-ups
Your doctor may advise you to return for regular check-ups. The frequency and nature of these check-ups will depend on your personal situation.

Contact your doctor as soon as possible if:
- you notice possible signs of thrombosis (e.g., severe pain and/or swelling in one of your legs, unexplained chest pain, breathlessness, or a sudden unusual cough, especially if you cough up blood);
- you suddenly have severe stomach pain or look jaundiced (indicating possible liver problems);
- you feel a lump in your breast;
- you have a sudden severe pain in the lower part of your belly or the stomach area (possibly indicating an ectopic pregnancy);
- you are to have surgery, or if you are confined to bed or cannot walk for a while (inform your doctor at least four weeks in advance);
- you have unexplained, heavy and prolonged vaginal bleeding;
- you suspect that you are pregnant.

Other medicines and Exluton
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Some medicines can reduce the efficacy of the pill. These include medicines used for the treatment of epilepsy (e.g. carbamazepine, oxcarbazepine, felbamate, primidone, phenytoin, phenobarbital, topiramate) or tuberculosis (e.g. rifampicin and rifabutine), HIV infections (e.g. ritonavir and nelfinavir) or other infectious diseases (e.g. griseofulvin), or activated charcoal used for gastro-
intestinal disturbances. Exluton can also intensify the effects of other medicines (e.g. ciclosporin) or reduce their efficacy.

Therefore, tell the doctor who is prescribing the pill what medicines you are taking. Also tell any other doctor or dentist who prescribes another medicine (or the dispensing pharmacist) that you use Exluton. They can then tell you if you need to use another non-hormonal contraceptive, and if so, for how long.

You must not take herbal remedies containing St John’s wort (mainly for mild depression) while taking Exluton. Simultaneous use can lead to reduced efficacy of the pill. Breakthrough bleeding and unwanted pregnancies have been reported as a result of simultaneous use. The reduced efficacy can last at least two weeks after stopping St John’s wort. Consult your doctor first if you plan to take herbal remedies while using Exluton.

**Pregnancy and breast-feeding**
If you are pregnant, think you are pregnant, want to get pregnant or are breastfeeding, contact your doctor or pharmacist before using this medicine.

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

**Breast-feeding**
Exluton does not influence the production or the quality of breast milk. Small amounts (0.14% of the amount ingested by the mother) of the active substance and Exluton metabolites pass through into breast milk, but there are no indications that this poses any risk for the baby. Tell your doctor if your baby shows any signs or symptoms which you think might be related to the use of Exluton.

**Driving and using machines**
There are no indications that Exluton affects concentration and alertness.

**Important information about some of the ingredients of Exluton**
Exluton contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before starting with Exluton.

### 3. How to take Exluton

**When and how to take the tablets**
The Exluton strip contains 28 tablets. On the back side of the strip, the days of the week are printed on the foil, with arrows printed between them. Each day corresponds to one tablet. Each time you start a new strip of Exluton, take a tablet in the top row. Start with the correct tablet. For example, if you start on a Wednesday, you must take the tablet from the top row marked (at the back) with WED. You continue to take one tablet a day until the strip is empty, always following the direction indicated by the arrows. By looking at the back of the strip, you can easily check whether you have taken your daily tablet. Take your tablet at about the same time each day. Swallow each tablet with water. You may have some bleeding while taking Exluton, which may look like a menstrual bleed, but you must continue to take your tablets. When a pack is empty, you must start with a new strip of Exluton on the next day – thus without interruption and without waiting for a period.

**Starting your first strip of Exluton**

*If you did not use an oral hormonal contraceptive in the past month*
Wait for your period. Take the first Exluton tablet on the first day of your menstrual period. Then you won’t have 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 (a condom) if you have sex. This condom advice applies to the first 7 days you take Exluton in the first cycle.

If you are switching from a combined hormonal contraceptive (combined oral contraceptive pill, vaginal ring or transdermal patch)
Start taking Exluton on the day after you take the last tablet of your present pill pack, or on the day of removal of your vaginal ring or patch (this means no tablet-, ring- or patch-free break). If your present pill pack also contains inactive tablets (placebo pills with no hormone), you must start Exluton on the day after taking the last active tablet (if you are not sure which this is, ask your doctor or pharmacist). It is not necessary to use an additional contraceptive method.

If you are switching from another progesterone-only oral contraceptive
You may stop taking it any day and start taking Exluton right away. You do not need to use an additional contraceptive method.

If you are switching from an injectable contraceptive, an implant or a hormone-releasing intrauterine device (IUD)
Start using Exluton when your next injection is due or on the day that your implant or your hormone-releasing IUD is removed. You do not need to use an additional contraceptive method.

After having a baby
If you have just had a baby, your doctor may tell you to wait until after your first normal period before you start taking Exluton. Sometimes it is possible to start sooner. Follow your doctor’s advice.

After a miscarriage or an abortion
Follow your doctor’s advice.

If you take more Exluton than you should
There have been no reports of serious harmful effects from taking too many Exluton tablets at a time. Symptoms that may occur are nausea, vomiting and, in women or girls, vaginal bleeding. Ask your doctor if you need advice.

If you forget to take Exluton
If you are less than 3 hours late taking a tablet, the reliability of Exluton 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 3 hours late in taking any tablet, the reliability of Exluton may be reduced. The more consecutive tablets you have missed, the higher the risk of reduced contraceptive efficacy. Take the last missed tablet as soon as you remember and take the next tablets at the usual times. Use a condom too 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 7 days before missing the tablets, there is a possibility of becoming pregnant. Ask your doctor for advice.

What to do if you have gastro-intestinal disturbances (e.g., vomiting, severe diarrhoea)
If you need to vomit within 3-4 hours after taking a tablet, or if you take activated charcoal or have severe diarrhoea, the active ingredient may not be completely absorbed. Follow the advice given above for if you forget to take tablets.

If you stop taking Exluton
You can stop taking Exluton whenever you want. If you do not want to become pregnant, ask your doctor about other birth control methods.
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.
4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects
Some serious side effects attributed to the use of the birth control pill are described in ‘What you need to know before you take Exluton’. Please read this section for additional information and consult your doctor at once if necessary.

Other possible side effects
Other side effects that are common (in less than 1 in 10 users) in users of Exluton or hormonal contraceptives in general are: headache, migraine, nausea, abdominal pain, acne, rash, painful bluish-red nodules (erythema nodosum), rash with red irregular spots (erythema multiforme), yellowish-brown pigment spots (chloasma), sensitivity to sunlight, weight gain, irregular vaginal bleeding, tender or painful breasts, nipple discharge, missed periods, mood swings, depression, lower sex drive and fluid retention.

Side effects that are uncommon (in less than 1 in 100 users) in users of Exluton or hormonal contraceptives in general are: vomiting, diarrhoea, breast enlargement, ovarian cysts (fluid-filled sacs in the ovaries), vaginal dryness, vaginal discharge and eye irritation when using contact lenses.

Side effects that are rare (in less than 1 in 1,000 users) in users of Exluton or hormonal contraceptives in general are: hives (urticaria), weight loss, greater sex drive and hypersensitivity reactions.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Dutch Pharmacovigilance Center Lareb, website www.lareb.nl. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Exluton

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

Store below 30°C. Do not freeze. Store in the original package to protect from light and moisture.
Do not use this medicine after the expiry date which is stated on the package and on the strip after ‘EXP:’. There is a month and year printed. The last day of the month is the expiry date.

Do not use Exluton if you notice that the tablets are discoloured or broken, or if you notice other visible signs of deteriorating quality.

6. Additional information

What Exluton contains
− The active ingredient is lynestrenol (500 micrograms)
− The other ingredients in this medicine are potato starch, amylopectin, lactose monohydrate and magnesium stearate.
What Exluton looks like and contents of the pack
One blister strip of Exluton contains 28 white round tablets with bevelled edges.
On one side the tablets are coded ‘TT’ above ‘2’, and on the other side ‘ORGANON*’. Each carton box contains 1 or 3 blister strips.
Not all package sizes may be available.

Marketing Authorisation Holder and Manufacturer
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Registered under number RVG 06443

This leaflet was last revised in May 2015.