

Exulenol



- You have unusual, heavy vaginal bleeding.
- You suspect that you are pregnant.
- The situation and symptoms mentioned above a described and explained in more detail elsewhere in this leaflet.

How do you use Exulenol?

- When and how to take the tablets ?

The Exulenol 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 Exulenol- take a tablet in the top row. Don't start with just any 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 pack is empty- always 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 Exulenol- but you must continue to take your tablets as normal. When a pack is empty- you must start with a new pack of Exulenol on the next day – thus without interruption and without waiting for a bleed.

- Starting your first pack of Exulenol:

• When no hormonal contraceptive has been used in the pill month,

start taking Exulenol on first day of your cycle, i.e. the first day of menstrual bleeding. Take a tablet marked with that day of the week. Exulenol 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 (barrier method) for the first 7 days of tablet-taking in the first cycle.

• When changing from a combined Pill

You can start taking Exulenol on the day after you take the last tablet from your present Pill pack (this means no tablet-free break). If your present in Pill pack also contains inactive tablets you can start Exulenol on the day after taking the last active tablet (if you are not sure which this is- ask your doctor or pharmacist). If you follow these instructions- it is not necessary to use an additional contraceptive method.

• When changing from another progestogen-only Pill (mini-pill)

You may stop taking it any day and start taking Exulenol right away. You need to use an addition contraceptive method (a barrier method) for the first 7 days of tablet taking when having intercourse. • When changing from an injectable or implant or a progestogen-releasing intrauterine device (IUD). Start using Exulenol when your next injection is due or on the day that your implant or your IUD is removed. You need to use an additional contraceptive method (a barrier method) for the first 7 days of tablet taking when having intercourse.

• 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 Exulenol. Sometimes it is possible to start sooner. Your doctor will advise you.

• After a miscarriage- or an abortion

Your doctor will advise you.

- If too many Exulenol tablets are taken (overdose)

There have been no reports of serious harmful effects from taking too many Exulenol tablets at one time. Symptoms that may occur are nausea- vomiting and- in women or girls- slight vaginal bleeding. For more information ask your doctor.

- When you want to stop taking Exulenol

You can stop taking Exulenol 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 do not want to become pregnant, ask your doctor about other methods of birth control.

- What to do if..... You forget tablets

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

• If you are more than 3 hours late in taking a tablet, the reliability of Exulenol 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 a condom too for the next 7 days of tablet-taking. If you missed one or more tablets in the week of tablet-intake and had intercourse in the week before missing the tablets- there is a possibility of becoming pregnant. Ask your doctor for advice.

..... you suffer from gastro-intestinal disturbances (e.g.- vomiting- severe diarrhea)

If you vomit- have severe diarrhea or take medical charcoal- the active ingredients of your Exulenol tablet may not have been completely absorbed. If you vomit or take medical charcoal within 3 hours after taking your tablet this is like missing a tablet. You need to take an extra tablet- and follow the advice for missed tablets.

..... you have unexpected bleeding

Vaginal bleeding may occur at irregular intervals during the use of Exulenol. This may be just slight staining which may not even require a pad- or heavier bleeding- which looks rather like a scanty period and requires sanitary protection. You may also not have any bleeding at all. The irregular bleeding are not a sign that the contraceptive protection of Exulenol is decreased. In general- you need not take any action; just continue to take Exulenol. If however- bleeding is heavy or prolonged consult your doctor.

What side effect might you have while taking Exulenol?

Like all medicines- Exulenol can have side effects.

Tell your doctor if you notice any unwanted effect- especially if severe or persistent- or if there is a change in your health that you think might be caused by Exulenol

a. Serious side effect.

Serious undesirable effect associated with the use of Exulenol are described in section 3 "What do you need to know before using Exulenol ?" please read this section for additional information and consult your doctor at once where appropriate.

b. Other possible side effects.

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

- breast tenderness- pain- enlargement and secretion;
- headache.
- Mood changes;
- contact lens intolerance.
- nausea, vomiting and other intestinal or stomach complaints.
- irregular bleeding, changes in vaginal secretion.
- various skin reactions.
- fluid retention.
- changes in body weight.
- hypersensitivity reactions.

If you notice any side effects not mentioned in this leaflet- please inform your doctor or pharmacist.

Storage Instructions:

Do not use after the expiry date stated on the package.

Do not store above 30 °C, do not refrigerate or freeze.

Store protected from light and moisture.

Keep your tablets out of reach of children.

Pharmaceutical Dosage Form:

Chemical Composition/Doses: Each tablet contains 0,5 mg of Lynestrenol.

Pharmacological Classifications: Hormons (Progestogens).

Type of pill:

Exulenol contains a small amount of one type of female sex hormone, the progestogen lynestrenol. For this reason Exulenol is called a progestogen- only-pill (POP), or a mini-pill.

Contrary to combined pills, mini-pill does not contain an estrogen hormone net to the progestogen.

The two main ways of action of Exulenol are:

- Prevention of the sperm cells from entering the womb.
- Mostly (in 70% of the women) no monthly release of an egg from the ovary occurs.

In contrast to the combined pill, Exulenol 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 during the use of Exulenol.

You also may not have any bleeding at all.

Indications:

To prevent pregnancy.

When Exulenol is taken correctly (without missing tablets), the chance of becoming pregnant is very low. One pack of Exulenol contains 28 white round tablets.

Do not use Exulenol:

Do not use Exulenol if you have any of the conditions listed below, if any of these apply to you, tell your doctor before starting to use Exulenol, your doctor may advise you 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 a cancer that grows under the influence of progestogens.
- If you have any unexplained vaginal bleeding.
- If you are allergic to any of the ingredients of Exulenol.
- If you are pregnant or think you might be pregnant.

If any of these conditions appear for the first time while using Exulenol you should consult your doctor promptly.

What do you need to know before using Exulenol?

1. General notes:

In this leaflet, several situations are described where you should stop taking the Exulenol, or where the reliability of the Exulenol may be decreased.

In such situations you should not have sex you should take extra non-hormonal contraceptive precautions. Do not use rhythm or temperature methods, these methods can be unreliable because the Exulenol alters the usual changes in temperature and cervical mucus that occur during the menstrual cycle. Exulenol like all contraceptive pills does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

2. Before you start to use Exulenol:

If Exulenol is used in the presence of any of the conditions listed below, you need to be kept under close observation.

Your doctor can explain to you what to do, therefore, if any these apply to you, tell your doctor before starting to use Exulenol:

- you have or have had cancer of the breast.
- you have cancer of the liver.
- You have never had thrombosis.
- you have diabetes.
- you have or have had a pregnancy outside the womb.
- You have or have had an infection or surgery of the fallopian tube.
- You suffer from epilepsy.
- You suffer from tuberculosis.
- You have or have had chloasma (yellowish-brown pigmentation on the skin, particularly of the face).

if so avoid so much exposure to the sun or ultraviolet radiation.

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

3. 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 women gets older. Therefore, the extra number of breast cancers diagnosed is higher among women who use the Pill at a higher age. How long a woman takes the Pill is less important.

4. The Pill and thrombosis:

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- but it is as high as the risk during pregnancy. The risk with Progestogens-only pills like Exulenol is believed to be lower than in users of Pill that also contain estrogens (combined Pill). If you notice doctor immediately, (see also "When should you contact your doctor?")

5. Ovarian Cysts:

During the use of all low-dose hormonal contraceptives 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.

6. The pill and breastfeeding:

Exulenol 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 in Exulenol pass over in breast milk and there are no indications of 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 Exulenol.

7. The Pill and pregnancy:

Exulenol must not be used by women who are pregnant- or who think they may be pregnant.

8. The Pill and ability to drive:

There are no indications of any effect of the use of Exulenol on the ability to drive.

9. The Pill and other medicines:

Some medicines may stop Exulenol 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, rifabutin) and HIV infections (e.g., ritonavir), medical charcoal used for stomach upset, and the herbal remedy st. john's wort (primarily used for the treatment of depressive moods). Exulenol may also interfere with the working of other medicines. Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines or herbal product, even those not prescribed. Also tell any other doctor or dentist who prescribes another medicine (or the dispensing pharmacist) that you use Exulenol. They can tell you if you need to take additional contraceptive precautions and if so- for how long.

When should you contact your doctor?

Regular check-ups

When you are using Exulenol, your doctor 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 as soon as possible if:

- Your notice possible signs of a thrombosis (e.g. severe pain or swelling in either or 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 have a lump in your breast.
- You have a sudden or severe pain in the lower part of your belly or the stomach area (possible indicating an ectopic pregnancy, this is a pregnancy outside the womb).
- You are to be immobilized (for example being confined to bed) or are to have surgery, consult your doctor at least four weeks in advance.

Lic.No: 480/2010

THIS IS A MEDICATIONS

A medication is a product but unlike any products.

A medication is a product which affects your health and its consumption contrary to instructions is dangerous for you. Follow strictly the doctors prescription, the method of use and the instructions of the pharmacist who sold the medication.

The doctor and the pharmacist are experts in medicines, their benefits and risks.

Do not by yourself interrupt the period of treatment prescribed.

Do not repeat the same prescription without consulting your doctor.

COUNCIL OF ARAB HEALTH MINISTERS KEEP MEDICATIONS OUT OF REACH OF CHILDREN ARAB PHARMACISTS ASSOCIATION

Produced by: International Drug Manufacturing - Syria - Aleppo

