

PACKAGE LEAFLET: INFORMATION FOR THE USER

Zumenon, coated tablets 2 mg
estradiol

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 pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
- 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 pharmacist.

Contents of this leaflet:

1. What is Zumenon and what is it used for?
2. When should you not use this medicine or be extra careful?
3. How to use this medicine?
4. Possible side effects
5. How to store this medicine?
6. Contents of the pack and other information

1. What is Zumenon and what is it used for?

Zumenon is a so-called hormone replacement therapy (HRT). It contains the female hormone estrogen. This medicine is intended for women after menopause who have not had a natural period for at least 6 months.

Zumenon is used for:

Relief of postmenopausal symptoms

During menopause, the amount of estrogen in the female body decreases significantly. This can cause symptoms such as a warm feeling in the face, neck, and chest ('hot flashes'). Zumenon relieves these symptoms after menopause. You will only be prescribed this medication if your symptoms significantly limit your daily functioning.

To prevent bone loss

After menopause, some women may develop brittle bones (osteoporosis). Your doctor will discuss the various treatments with you. If you have an increased risk of bone fractures due to bone loss and other treatments are not suitable for you, you can use Zumenon to prevent bone loss after menopause.

How does Zumenon work?

The estradiol in Zumenon replaces the estrogen that you produce in your ovaries from puberty until menopause and it reduces the symptoms of your menopause. Estradiol also provides protection against osteoporosis.

If your uterus has not been removed, you must also use a progestogen (such as dydrogesterone) for a number of days per month in addition to Zumenon to prevent abnormal growth of the uterine lining.

There is limited experience in women over 65 years of age.

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

Medical history and regular check-ups

It is important to weigh the risks of hormone replacement therapy (HRT) against the benefits before starting this medication or deciding to continue with it.

There is limited experience in treating women with premature menopause (due to ovarian problems or after surgery). If you have premature menopause, the risks of HRT use may be different. Discuss this with your doctor.

Before you start (or restart) HRT, your doctor will ask you several questions about your medical history and that of your family. Your doctor may decide to perform a physical examination and, if necessary, a breast exam and/or internal examination.

Once you have started with Zumenon, you should regularly visit your doctor for check-ups (at least once a year). During these check-ups, you will discuss the pros and cons of continuing the treatment.

Have regular mammograms (X-rays) according to your doctor's advice.

When should you not use this medicine?

If any of the following situations apply to you, you should not use this medicine. If you are unsure, consult your doctor before starting the treatment.

Do not use this medicine:

- if you are allergic to any of the ingredients in this medicine; you can find these ingredients in section 6;
- if you have or have had breast cancer, or if breast cancer is suspected;
- if you have a malignant tumor that is sensitive to estrogen or if it is suspected that you have this (e.g., a tumor of the endometrium);
- if you have vaginal bleeding of unknown cause;
- if you have abnormal growth of the endometrium (endometrial hyperplasia) and you are not being treated for it;
- if you have or have ever had a blood clot in a vein (thrombosis), such as in the legs (deep vein thrombosis) or in the lungs (pulmonary embolism);
- if you have a blood clotting disorder (such as protein C, protein S, or antithrombin deficiency);
- if you have recently had a blockage in an artery or if you currently have one, such as a heart attack, stroke, or angina pectoris (severe chest pain due to lack of oxygen);
- if you have or have ever had liver disease and your liver function has not yet returned to normal;
- if you have a congenital disorder in the production of the red pigment of the blood (porphyria).

If you develop any of the above conditions for the first time while using this medicine, you must stop using it immediately and contact your doctor.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine. If you have or have had any of the conditions listed below, you should see your doctor more often for check-ups, as they may recur or worsen during treatment with this medicine:

- a benign tumor in the uterus (also called a 'fibroid');
- a condition where the endometrium is also located outside the uterus (endometriosis);
- abnormal growth of the endometrium (endometrial hyperplasia);
- an increased risk of blood clots (see 'Blood clots in a vein (thrombosis)');
- an increased risk of estrogen-sensitive cancer, e.g., if your mother, sister, or grandmother has had breast cancer;
- high blood pressure;
- a liver disorder, such as a benign liver tumor;
- diabetes;
- gallstones;
- migraine or severe headache;
- systemic lupus erythematosus (SLE; a specific immune system disorder that can occur in many parts of the body);
- epilepsy;
- asthma;
- an ear disorder with hearing loss (otosclerosis);
- an increased fat level in your blood (triglycerides);
- fluid retention due to heart or kidney problems;
- hereditary or acquired angioedema.

Stop using this medicine immediately and contact your doctor if any of the following situations occur:

- one of the conditions under "When should you not use this medicine";
- yellowing of the skin or the whites of the eyes (jaundice); this may be a sign of a liver disorder;
- symptoms of angioedema such as swelling of the face, tongue and/or throat and/or difficulty swallowing or a skin rash with pink bumps and severe itching (hives or urticaria), along with difficulty breathing;
- a significant increase in your blood pressure (symptoms include headache, fatigue, and dizziness);
- migraine-like headache that you experience for the first time;
- you become pregnant;
- you notice signs of a blood clot, such as:
 - painful swelling and redness of the legs
 - sudden chest pain
 - difficulty breathing.

For more information, see 'Blood clot in a vein (thrombosis)'.

Note: Zumenon is not a contraceptive. If you have had a menstrual period in the last 12 months or are under 50 years old, you may still need to use contraceptives to prevent pregnancy. Consult your doctor for advice.

HRT and cancer

Abnormal growth of the uterine lining (endometrial hyperplasia) and cancer of the uterine lining (endometrial cancer)

Use of HRT with estrogen alone increases the risk of excessive growth of the uterine lining (endometrial hyperplasia) and cancer of the uterine lining (endometrial cancer).

You are protected against this additional risk by taking progestogen tablets for at least 12 days of each 28-day cycle in addition to estrogen. Your doctor will therefore prescribe progestogen separately if you still have your uterus. If your uterus has been removed, discuss with your doctor whether you can safely use this medicine without the addition of progestogen.

Of the women aged 50 to 65 who still have their uterus and do not use HRT, an average of 5 per 1,000 will develop endometrial cancer. Of the women aged 50 to 65 who still have their uterus and use HRT with estrogen alone, between 10 and 60 per 1,000 women will develop endometrial cancer (i.e., 5 to 55 extra cases per 1,000), depending on the dose and duration of treatment.

Irregular bleeding

You may experience irregular bleeding or small amounts of blood loss ('spotting') during the first 3-6 months of treatment. However, if the irregular bleeding persists beyond the first 6 months starts after you have been using Zumenon for more than 6 months persists after you have stopped using Zumenon you should contact your doctor as soon as possible.

Breast cancer

Research has shown that the use of hormone replacement therapy (HRT) with an estrogen-progestogen combination or HRT with estrogen alone increases the risk of breast cancer. The additional risk depends on how long you use HRT. The additional risk occurs after 3 years of use. After stopping HRT, the additional risk will decrease again, but if you have used HRT for more than 5 years, the additional risk may persist for 10 years or longer.

Comparison

Of the women aged 50 to 54 who do not use HRT, an average of 13 to 17 per 1,000 will develop breast cancer over a 5-year period.

Of the women aged 50 who use HRT with estrogen alone for 5 years, there will be 16-17 cases per 1,000 users (i.e., 0 to 3 extra cases).

Of the women aged 50 who start HRT with an estrogen-progestogen combination over a 5-year period, there will be 21 cases per 1,000 users (i.e., 4 to 8 extra cases).

Of the women aged 50 to 59 who do not use HRT, an average of 27 per 1,000 women will develop breast cancer over a 10-year period.

Of the women aged 50 who use estrogen-only HRT for 10 years, there will be 34 cases per 1,000 users (i.e., 7 extra cases).

Of the women aged 50 who use combined estrogen-progestogen HRT for 10 years, there will be 48 cases per 1,000 users (i.e., 21 extra cases).

Regularly check your breasts. Contact your doctor if you notice any changes, such as:

- dimpling of the skin.
- changes in the nipple.
- lumps that you can see or feel.

Ovarian cancer

Ovarian cancer is rare, much rarer than breast cancer. A slight increase in the risk of ovarian cancer has been reported with the use of estrogen therapy or a combination of estrogen/progestogen HRT.

The risk of ovarian cancer depends on age. Of the women aged 50 to 54 who do not use HRT, about 2 in 2,000 women will be diagnosed with ovarian cancer over a 5-year period. Among women who have used HRT for 5 years, there are about 3 cases per 2,000 users (i.e., about 1 extra case).

HRT and effects on heart and circulation

Blood clot in a vein (thrombosis)

Women who use HRT have about a 1.3 to 3 times higher chance of developing a blood clot in the veins than women who do not use HRT, especially during the first year of treatment.

A blood clot can be serious, and if it reaches the lungs, it can lead to chest pain, shortness of breath, fainting, and even death.

The risk of a blood clot increases as you get older and if any of the following situations apply to you. Inform your doctor in the following cases:

- you are unable to walk for a long time due to surgery, injury, or illness (see also section 3 'If you need to have surgery');
- you are severely overweight (BMI > 30 kg/m²);
- you have a blood clotting disorder for which you need to use medication long-term to prevent blood clots; use to prevent blood clots;
- one of your close family members has ever had a blood clot in the legs, lungs, or another organ; another organ;
- you have systemic lupus erythematosus (SLE);
- you have cancer.

For signs of a blood clot, see 'Stop using this medicine immediately and contact your doctor'.

Comparison

Of the women in their fifties who do not use HRT, an average of 4 to 7 out of 1,000 will have a blood clot over a period of 5 years.

Of the women in their fifties who use HRT with estrogen and progestogen for more than 5 years, there are between 9 and 12 cases per 1,000 (i.e., 5 extra cases per 1,000).

Among women in their fifties who have had their uterus removed and use HRT with estrogen only for more than 5 years, there are 5 to 8 cases of thrombosis per 1,000 users (i.e., 1 extra case per 1,000).

Heart disease (heart attack)

There is no evidence that HRT helps prevent a heart attack.

Women over 60 who use HRT with estrogen and progestogen have a slightly higher chance of developing heart disease than women who do not use HRT.

Women who have had their uterus removed and use HRT with estrogen only do not have a higher chance of heart disease.

Stroke

The risk of stroke is about 1.5 times higher in women who use HRT than in women who do not use HRT. The number of extra cases of stroke due to HRT increases with age.

Comparison

Of the women in their fifties who do not use HRT, an average of 8 out of 1,000 will have a stroke over a period of 5 years. Among women in their fifties who use HRT, there are 11 cases of stroke per 1,000 users over a period of 5 years (i.e., 3 extra cases per 1,000).

Other conditions

HRT does not work to prevent memory loss. There is evidence that there is a greater chance of memory loss in women who start using HRT after their 65th year. Ask your doctor for advice.

Are you using any other medicines?

Are you using any other medicines besides Zumenon, or have you done so recently, or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist. This also applies to medicines for which you do not need a prescription, as well as herbal and natural medicines.

Some medicines reduce the effectiveness of Zumenon, which may cause you to have irregular bleeding. This applies to:

- medicines for epilepsy (such as phenobarbital, carbamazepine, phenytoin);
- medicines for tuberculosis (such as rifampicin, rifabutin);
- medicines for an HIV infection (such as nevirapine, efavirenz, ritonavir, and nelfinavir);
- herbal medicines containing St. John's wort (*Hypericum perforatum*).

HRT can affect the effectiveness of some other medicines:

- a medicine for epilepsy (lamotrigine), because this can increase the frequency of epileptic seizures;
- medicines for hepatitis C virus (HCV) (such as combination treatments ombitasvir/paritaprevir/ritonavir and dasabuvir with or without ribavirin; glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir) can cause an increase in liver function blood values (increase of ALT liver enzyme) in women using combined hormonal contraceptives containing ethinylestradiol. Zumenon contains estradiol instead of ethinylestradiol. It is not known whether an increase in ALT liver enzyme can occur when Zumenon is used with this HCV combination treatment.

Are you using any other medicines besides Zumenon, have you done so recently, or might you do so soon? This also applies to medicines you can get without a prescription, herbal medicines, or other natural products. Then tell your doctor or pharmacist.

Laboratory tests

If your blood is being tested, you must tell the doctor or technician that you are using Zumenon, as it may affect the results of some tests.

Pregnancy and breastfeeding

Zumenon is intended for use only in postmenopausal women. If you become pregnant, stop using Zumenon immediately and contact your doctor.

Driving ability and the use of machines

The effect of Zumenon on driving ability or the use of machines has not been studied. However, an effect is unlikely.

Zumenon contains lactose

If your doctor has told you that you cannot tolerate certain sugars, contact your doctor before taking this medicine.

3. How to use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

When should you start using Zumenon?

You can start Zumenon on any convenient day if you:

- are not currently using an HRT product;
- are switching from a continuous combined HRT product; this is when you use a tablet or patch every day that contains both substances (estrogen and progestogen).

You start using Zumenon the day after finishing your 28-day cycle if you:

- are being switched from a 'cyclic' or 'sequential' HRT medicine; this is the case if you take an estrogen tablet or use an estrogen patch in the first part of your cycle, followed by a tablet or patch with both (estrogen and progestogen) for 14 days.

Use of this medicine

Take the tablet with water.

Take the tablet with or without food.

Try to take the tablet at the same time every day. This ensures a constant amount of the medicine in your body. It will also help remind you to take your tablets.

Take one tablet every day without a break between packs. The strips are marked with the days of the week to help you remember when to take your tablets.

How much should you take?

Your doctor will prescribe the lowest possible dose for the shortest possible time to treat your symptoms. If necessary, they may increase the dose. Discuss with your doctor if you feel the dose is too high or too low.

If you are using Zumenon to prevent bone loss, your doctor will adjust the dosage to your needs. This will depend on your bone mass.

If you need to undergo surgery

If you need to undergo surgery, tell the doctor that you are using Zumenon. You should stop using this medicine about 4 to 6 weeks before the surgery to reduce the risk of a blood clot (see section 2, 'Blood clot in a vein'). Ask your doctor when you can start using this medicine again.

Have you taken too much of this medicine?

You may feel nauseous, sleepy, or dizzy, or you may vomit, or you may experience withdrawal bleeding. Treatment is probably not necessary, but if you are concerned, you can ask your doctor for advice.

This information also applies to children who have taken too much of this medicine.

Have you forgotten to take this medicine?

Take the missed tablet as soon as you remember. If more than 12 hours have passed since you should have taken your tablet, take the next dose at the usual time and do not take the missed tablet. Do not take a double dose to make up for a forgotten dose. If you have missed a dose, bleeding or spotting may occur.

If you stop taking this medicine

Do not stop taking Zumenon without prior consultation with your doctor.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

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

The following conditions have been reported more frequently in women using HRT than in women not taking HRT:

- breast cancer
- abnormal growth or cancer of the lining of the womb (endometrial hyperplasia or cancer)
- ovarian cancer
- blood clot in a vein in the legs or lungs (venous thromboembolism)
- heart disease
- stroke
- possible memory loss when HRT is started after age 65^e year.

See section 2 for more information about these side effects.

Assessment of side effects is based on the following frequencies:

Very common:	Occur in more than 1 in 10 users
Common:	Occur in less than 1 in 10 users
Uncommon:	Occur in less than 1 in 100 users
Rare:	Occur in less than 1 in 1,000 users
Very rare:	Occur in less than 1 in 10,000 users
Not known:	Cannot be determined from the available data

Common:

- weight gain or weight loss;
- headache
- nausea; abdominal pain; flatulence
- skin rash; itching (pruritus)
- leg cramps

irregular bleeding, breakthrough bleeding and uterine and vaginal bleeding including light bleeding between periods (spotting); pelvic pain
feeling of weakness (asthenia)

Sometimes:

vaginal yeast infection caused by a fungus called *Candida albicans*
increase in uterine fibroids
hypersensitivity
depression; nervousness
dizziness
visual disturbances
palpitations
increased blood pressure, narrowing of the blood vessels in the legs or arms that restricts blood flow (peripheral vascular disease); varicose veins; blood clots in the legs or lungs (venous thromboembolism)
digestive disorder (dyspepsia)
gallbladder disorder
hives (urticaria); painful, bluish-red nodules in the skin (erythema nodosum)
cystitis-like symptoms
back pain
breast pain or tender breasts
fluid retention in the skin, usually observed as swelling of the ankles (peripheral edema)

Rare:

anxiety; altered sexual desire (libido change)
migraine
intolerance to contact lenses
bloating; vomiting
abnormal liver function, which may include yellowing of the skin (jaundice)
excessive hair growth in women (hirsutism); acne
muscle cramps
painful menstruation (dysmenorrhea); vaginal discharge; breast swelling; premenstrual syndrome (PMS)
fatigue

Very rare:

deficiency of red blood cells (hemolytic anemia)
involuntary muscle contractions (chorea)
heart attack (myocardial infarction)
stroke (see "Heart conditions (coronary artery disease (CAD))" for more information)
swelling of the skin of the face and throat. This can cause breathing difficulties (angioedema); red spots on the skin (erythema multiforme); purplish spots or pinpoint bleeding on the skin (purpura); skin discoloration that may persist after treatment with the drug (chloasma)
exacerbation of porphyria (a rare blood pigment disorder)

Frequency not known:

changes to the breasts (cysts and connective tissue)

Other side effects reported with the use of estradiol. Frequency not known:

a disease of the immune system that affects many organs in the body (systemic lupus erythematosus)
increased level of certain fats in the blood (hypertriglyceridemia)
worsening epilepsy
possible dementia when you are over 65 years old
blood clot in the arteries
inflammation of the pancreas in women who already had an increased level of certain fats in the blood
reflux of stomach contents into the esophagus
urinary incontinence
increase in the total amount of thyroid hormones.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you can help us obtain 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 use this medicine after the expiry date. It can be found on the strip after exp. It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer need. They will be destroyed responsibly and will not enter the environment.

6. Contents of the packaging and other information

What substances are in this medicine?

The active substance in this medicine is: estradiol.

The other substances in this medicine are lactose monohydrate, talc, corn starch, magnesium stearate, hypromellose, colloidal anhydrous silica, macrogol 400, and the colorants titanium dioxide (E171) and iron oxides (E172).

What does Zumenon look like and how much is in a package?

Zumenon, coated tablets: round, biconvex, brick-red, coated tablets, with the imprint '379' on one side.

Zumenon is available in a calendar pack with 28 tablets.

Marketing authorization holder
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