

Zumenon®

estradiol hemihydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Zumenon.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

When you must not use Zumenon

Do not use Zumenon or other estrogens, with or without progestogen to prevent heart attacks, stroke or dementia.

A study called the Women's Health Initiative indicated increased risk of stroke, breast cancer, and blood clots in the legs or lungs in women receiving treatment with a product containing conjugated estrogens 0.625 mg and the progestogen medroxyprogesterone acetate (MPA). The researchers stopped the study after 5 years when it was determined the risks were greater than the benefits in this group.

This Women's Health Initiative also indicated increased risk of stroke, and blood clots in the legs or lungs in women receiving treatment with

a product containing conjugated estrogens 0.625 mg alone. The researchers stopped the study after 7 years when it was determined the risks were greater than benefit in this group.

The Women's Health Initiative Memory Study indicated increased risk of dementia in women aged 65 years or older taking conjugated estrogens and MPA. Increased risk of dementia was also reported in women taking conjugated estrogens alone. There are no comparable data currently available for other doses of conjugated estrogens and MPA or other combinations of estrogens and progestogens. Therefore, you should assume the risks will be similar for other medicines containing estrogen and progestogen combinations.

Talk regularly with your doctor about whether you still need treatment with Zumenon.

Treatment with estrogens, with or without progestogens should be used at the lowest effective dose and for the shortest period of time.

What Zumenon is used for

Zumenon is a type of treatment called hormone replacement therapy (HRT). Zumenon tablets contain a hormone called estradiol.

This medicine helps to relieve the symptoms many women feel during and after menopause. Zumenon may be used by women who still have a uterus (womb). Menopause may be natural or occur after surgery or medical treatment.

Women with an intact womb should generally be prescribed Zumenon and another medicine, a progestogen, to protect the lining of the uterus from over stimulation.

HRT should not be used for the long-term maintenance of general health or to prevent heart disease or dementia.

Zumenon is not suitable for birth control and it will not restore fertility.

How it works

Estradiol is a natural female sex hormone called an estrogen. It is the same hormone that your ovaries were producing before the menopause.

Menopause generally occurs between the ages of 45 and 55, because your body's production of estrogen decreases. It may happen sooner if the ovaries are removed by surgery (e.g. total hysterectomy). This can cause unpleasant symptoms such as a feeling of warmth in the face, neck and chest, "hot flushes" (sudden intense feelings of heat and sweating throughout the body), sleep problems, irritability and depression. Some women also have problems with urine control or with dryness of the vagina causing discomfort during or after sex. Estrogens can be given to reduce or eliminate these symptoms.

Ask your doctor if you have any questions about why it has been prescribed for you.

Your doctor may have prescribed it for another purpose.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

Before you take Zumenon

When you must not take it

HRT should only be used if you have been fully informed of the risks.

The decision to use HRT should be based on your symptoms and health, and made after a careful medical evaluation.

Do not take Zumenon if you have an allergy to:

- any medicine containing estradiol
- any of the ingredients listed at the end of this leaflet

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Do not take Zumenon if you have or have had:

- Cancer of the breast or uterus (endometrium) or any other estrogen dependent cancer
- Blood clots. Painful inflammation of the veins or blockage of a blood vessel in the legs, lungs, brain or heart
- Any condition that increases the tendency for you to get blood clots
- Abnormal vaginal bleeding
- Severe liver disease
- A condition called porphyria
- Hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption

If you are not sure whether any of the above conditions apply to you, your doctor can advise you.

Do not take this medicine if you are pregnant. Discuss with your

doctor if you are planning on becoming pregnant.

Do not breastfeed if you are taking this medicine.

You must stop taking Zumenon 4 weeks before certain types of surgery.

Do not take it after the expiry date printed on the pack or if the packaging is damaged or shows signs of tampering.

If it has expired or is damaged return it to your pharmacist for disposal.

Before you start to take it

Tell your doctor or pharmacist if you have any allergies to any other medicines, foods, preservatives or dyes.

You must have a through medical check-up before starting HRT for the first time or recommencing HRT.

Tell your doctor if you have or have had any of the following medical conditions:

- a family history of breast cancer
- nodules, lumps or cysts in your breasts or any other benign breast condition (not cancerous)
- fibroids or other benign tumours of the uterus (not cancerous)
- ovarian cancer
- unusual or irregular bleeding or spotting from the vagina
- endometriosis
- liver problems, including yellowing of the skin and whites of the eyes and a condition called porphyria
- cholestatic jaundice (obstruction of the bile duct)
- kidney problems
- high blood pressure
- heart problems
- diabetes
- migraine or severe headaches
- asthma
- epilepsy

- gall bladder disease
- a high level of triglycerides (fats) in the blood
- high or low levels of calcium in the blood
- abnormal vision
- hypothyroidism
- hearing loss due to a problem with the bones in the ear called otosclerosis

Tell your doctor if you are likely to have an increased risk of developing blood clots in your blood vessels.

The risk increases as you get older and it may also be increased if:

- anyone in your immediate family has ever had blood clots in the blood vessels of the legs or lungs
- you are overweight
- you have varicose veins
- you have a disorder called systemic lupus erythematosus

If you have not told your doctor about any of the above, tell them before you take Zumenon.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.

Some medicines and Zumenon may interfere with each other. These include:

- herbal medicines containing St John's Wort
- some medicines used to treat epilepsy
- some antibiotic and anti-infective medicines
- some medicines which require precise dosing e.g. tacrolimus, ciclosporin, fentanyl and theophylline

These medicines may be affected by Zumenon, or may affect how well it works. You may need to use

different amounts of your medicine, or take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking Zumenon.

Special Warning

Treatment with estrogens alone over a prolonged period may expose women with an intact womb to an increased risk of cancer of the lining of the womb.

How to take Zumenon

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

The usual dose is one tablet daily.

If you have not had a period for twelve months or more or if you have had a hysterectomy, you can start Zumenon immediately.

If you are having irregular periods, start taking Zumenon on day 5 of the menstrual cycle.

If your uterus is still intact your doctor will generally prescribe another medicine (progesterone) to take with Zumenon during part of your menstrual cycle.

How to take it

Swallow the tablet whole with a glass of water.

When to take it

Take Zumenon at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

The pack is labelled with the days of the week to help you with taking your tablets every day.

You should start each new pack the day after you have finished the current pack. Do not leave a gap between packs.

How long to take it

Your doctor can advise you how long you may need to take Zumenon.

Your doctor can discuss the risks and benefits of long-term treatment with HRT. Some recent studies have shown that women using HRT have a small increase in breast cancer risk after several years of use. The risk increases with the length of HRT use.

Recent studies have also shown that HRT is associated with a small increase in the risk of heart attacks, strokes, blood clots, including clots in the lungs. However, the risk of hip fractures and bowel cancer may be reduced.

Another study has shown that in women older than 65 years, HRT is associated with a small increase in the risk of dementia, including Alzheimer's disease. It is not known if this finding applies to younger women.

Continue taking Zumenon for as long as your doctor recommends.

If you forget to take it

If it is less than 12 hours before your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for advice.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (13 11 26), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Zumenon. Do this even if there are no signs of discomfort or poisoning.

While you are taking Zumenon

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Zumenon.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

Tell your doctor that you are using Zumenon well in advance of any expected hospitalisation or surgery. If you go to hospital unexpectedly, tell the doctor who admits you that you are using it.

The risk of developing blood clots in your blood vessels may be temporarily increased after surgery, serious injury or having to stay in bed for a long period of time. If possible, Zumenon should be stopped at least 4 weeks before surgery and it should not be restarted until you are fully mobile.

Tell your doctor immediately if you have any sore veins or suspected blood clots, disturbances in vision, sudden onset of migraine, significant increase in blood pressure, or yellowing of the skin or eyes (jaundice) while taking Zumenon tablets.

If you are still having periods of any kind, you should continue to use non-hormonal contraceptive

methods (such as a condom) to prevent pregnancy.

If you become pregnant while using Zumenon, tell your doctor immediately.

Zumenon should not be used while you are pregnant.

Check your breasts each month and report any changes promptly to your doctor. Particularly if you have breast lumps or a family history of breast cancer.

See your doctor at least once a year for a check-up. Some women will need to go more often. Your doctor may:

- check your breasts and order a mammogram at regular intervals
- check your uterus and cervix and do a pap smear at regular intervals
- check your blood pressure and cholesterol level.

Things you must not do

Do not use this medicine to treat any other complaints unless your doctor or pharmacist tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not stop taking Zumenon, or change the dosage, without checking with your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Zumenon.

All medicines have some unwanted side effects. Sometimes they are serious but most of the time they are not. You may need medical attention if you get some of the side-effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following:

- irregular vaginal bleeding or spotting (if bleeding is heavy, check with your doctor as soon as possible)
- tender, painful or swollen breasts
- period-like pain
- vaginal itching, inflammation or discharge
- swelling of the lower legs, ankles, fingers or abdomen due to fluid retention
- nausea (feeling sick), abdominal pain or tenderness, vomiting, heartburn, bloating, diarrhoea
- headache, migraine
- rise in blood pressure, palpitations
- fatigue or dizziness
- depression, anxiety
- back pain, muscle cramps
- change in sex drive
- weight change
- acne, itchy or dry skin, skin discolouration
- unusually excessive hair growth
- vision changes
- contact lens intolerance

The above list includes the more common side effects of your medicine.

They are usually mild however tell your doctor or pharmacist if you notice anything that is making you feel unwell.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other part of the body; shortness of breath, wheezing or troubled breathing
- signs that blood clots may have formed, such as sudden severe

headache, loss of coordination, blurred or loss of vision, slurred speech, numbness or tingling, painful swelling in the calves or thighs, chest pain, coughing blood

- pain or tenderness in the abdomen, which may be accompanied by fever, loss of appetite, nausea and vomiting
- chest pain
- difficulty breathing
- new onset migraine-like headache
- a yellow colour to the skin or eyes, itching, dark coloured urine or light-coloured bowel motions.
- sudden loss of vision

The above list includes very serious side effects. You may need urgent medical attention. These side effects are rare.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some people.

After using Zumenon

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the box or the blister pack they may not keep well.

Keep the medicine in a cool, dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill. Do not leave it in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking this medicine, or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Australian Registration Number:

AUST R 75888

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Product description

What it looks like

Zumenon tablets are round, biconvex, brick-red, film-coated tablets of 7mm diameter each containing 2 mg estradiol bearing the inscription "379" on one side.

Zumenon is available in boxes of 56 tablets.

Ingredients

Each Zumenon tablet contains 2 mg of estradiol (as hemihydrate) as the active ingredient:

It also contains:

- lactose monohydrate
- hypromellose
- maize starch
- colloidal anhydrous silica
- magnesium stearate
- Opadry complete film coating system OY-6957 Pink

Zumenon tablets do not contain gluten. Zumenon tablets contain sugars (as lactose).

Supplier

Zumenon is made in the Netherlands.

Zumenon is supplied in Australia by:

Mylan Health Pty Ltd

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.mylan.com.au
Phone: 1800 314 527

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