

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. When you must not use ZUMENON?

Do not use ZUMENON or other estrogens, with or without progestogen to prevent heart attacks, stroke or dementia. Talk regularly with your doctor about whether you still need treatment with ZUMENON.

For more information, see Section [1. When you must not use ZUMENON?](#) in the full CMI.

### 2. Why am I using ZUMENON?

ZUMENON contains the active ingredient estradiol hemihydrate. ZUMENON is a type of treatment called hormone replacement therapy (HRT) that helps to relieve the symptoms many women feel during and after menopause.

For more information, see Section [2. Why am I using ZUMENON?](#) in the full CMI.

### 3. What should I know before I use ZUMENON?

Do not use if you have ever had an allergic reaction to any medicine containing estradiol or any of the ingredients listed at the end of this leaflet. HRT should only be used if you have been fully informed of the risks. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [3. What should I know before I use ZUMENON?](#) in the full CMI.

### 4. What if I am taking other medicines?

Some medicines may interfere with ZUMENON and affect how it works.

A list of these medicines is in Section [4. What if I am taking other medicines?](#) in the full CMI.

### 5. How do I use ZUMENON?

- The usual dose is one tablet daily.
- Swallow the tablet whole with a glass of water. Take ZUMENON at about the same time each day.

More instructions can be found in Section [5. How do I use ZUMENON?](#) in the full CMI.

### 6. What should I know while using ZUMENON?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using ZUMENON.</li><li>• 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.</li><li>• 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.</li><li>• If you become pregnant while using ZUMENON, tell your doctor immediately.</li><li>• Check your breasts each month and report any changes promptly to your doctor.</li><li>• See your doctor at least once a year for a check-up.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not use this medicine to treat any other complaints unless your doctor or pharmacist tells you to.</li><li>• Do not stop taking ZUMENON, or change the dosage, without checking with your doctor.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep the medicine in a cool, dry place where the temperature stays below 30°C.</li></ul>

For more information, see Section [6. What should I know while using ZUMENON?](#) in the full CMI.

### 7. Are there any side effects?

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

For more information, including what to do if you have any side effects, see Section [7. Are there any side effects?](#) in the full CMI.

# ZUMENON<sup>®</sup>

Active ingredient(s): *estradiol hemihydrate*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using ZUMENON. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ZUMENON.**

**Where to find information in this leaflet:**

- [1. When you must not use ZUMENON?](#)
- [2. Why am I using ZUMENON?](#)
- [3. What should I know before I use ZUMENON?](#)
- [4. What if I am taking other medicines?](#)
- [5. How do I use ZUMENON?](#)
- [6. What should I know while using ZUMENON?](#)
- [7. Are there any side effects?](#)
- [8. Product details](#)

### 1. 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.

### 2. Why am I using ZUMENON?

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.

### 3. What should I know before I use ZUMENON?

#### Warnings

**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 use ZUMENON if:

- you are allergic to any medicine containing estradiol or 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.

- 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.**

**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 thorough 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
- hereditary angioedema or acquired angioedema

**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.**

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [7. Are there any side effects?](#)

### **Pregnancy and breastfeeding**

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.

### **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.

## **4. What if I am taking other medicines?**

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

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

- herbal medicines containing St John's Wort
- some medicines used to treat epilepsy, e.g. lamotrigine
- some antibiotic and anti-infective medicines
- some medicines which require precise dosing e.g. tacrolimus, ciclosporin, fentanyl and theophylline
- the hepatitis C treatment combination regimen of ombitasvir/paritaprevir/ritonavir with and without dasabuvir

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.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ZUMENON.**

## 5. How do I use 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 much to take

- Swallow the tablet whole with a glass of water.

### When to take ZUMENON

- **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 ZUMENON

**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 ZUMENON

If you think that you have used too much ZUMENON, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 6. What should I know while using ZUMENON?

### Things you should 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 should 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.

### Looking after your medicine

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

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

### Keep it where young children cannot reach it.

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

### Getting rid of any unwanted medicine

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.

Do not use this medicine after the expiry date.

## 7. Are there any 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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• irregular vaginal bleeding or spotting (if bleeding is heavy, check with your doctor as soon as possible)</li> <li>• tender, painful or swollen breasts</li> <li>• period-like pain</li> <li>• vaginal itching, inflammation or discharge</li> <li>• swelling of the lower legs, ankles, fingers or abdomen due to fluid retention</li> <li>• nausea (feeling sick), abdominal pain or tenderness, vomiting, heartburn, bloating, diarrhoea</li> <li>• headache, migraine</li> <li>• rise in blood pressure, palpitations</li> <li>• fatigue or dizziness</li> <li>• depression, anxiety</li> <li>• back pain, muscle cramps</li> <li>• change in sex drive</li> <li>• weight change</li> <li>• acne, itchy or dry skin, skin discolouration</li> <li>• unusually excessive hair growth</li> <li>• vision changes</li> <li>• contact lens intolerance</li> </ul>	<p>Tell your doctor or pharmacist if you notice any of these common side effects. They are usually mild however tell your doctor or pharmacist if you notice anything that is making you feel unwell.</p>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• 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</li> <li>• 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</li> <li>• pain or tenderness in the abdomen, which may be accompanied by fever, loss of appetite, nausea and vomiting</li> <li>• chest pain</li> <li>• difficulty breathing</li> <li>• new onset migraine-like headache</li> <li>• a yellow colour to the skin or eyes, itching, dark coloured</li> </ul>	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects. These side effects are rare.</p>

Serious side effects	What to do
urine or light-coloured bowel motions. • sudden loss of vision	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

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

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 8. Product details

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

### What ZUMENON contains

<b>Active ingredient (main ingredient)</b>	2 mg of estradiol (as hemihydrate)
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• lactose monohydrate</li> <li>• hypromellose</li> <li>• maize starch</li> <li>• colloidal anhydrous silica</li> <li>• magnesium stearate</li> <li>• Opadry complete film coating system OY-6957 Pink (ARTG PI No: 4158)</li> </ul>
<b>Potential allergens</b>	ZUMENON tablets contain sugars as lactose.

**Do not take this medicine if you are allergic to any of these ingredients.**

### What ZUMENON looks like

ZUMENON tablets are round, biconvex, brick-red, film-coated tablets of 7 mm diameter each containing 2 mg estradiol bearing the inscription "379" on one side. (AUST R 75888).

ZUMENON is available in boxes of 56 tablets.

ZUMENON is made in the Netherlands.

### Who distributes ZUMENON

Viatrix Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatrix.com.au](http://www.viatrix.com.au)

Phone: 1800 274 276

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