Zumenon® 2 mg

film-coated tablets

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

pharma code

1. WHAT ZUMENON IS AND WHAT IT IS USED FOR

Zumenon is a Hormone Replacement Therapy (HRT). It contains the female hormone oestrogen. Zumenon is used in postmenopausal women with at least 6 months since their last natural period and women switching from standard (cyclic or sequential) HRT on the advice of their doctor.

Zumenon is used for:

Relief of symptoms occurring after menopause

During the menopause, the amount of the oestrogen produced by a woman's body drops. This can cause symptoms such as hot face, neck and chest ("hot flushes"). Zumenon alleviates these symptoms after menopause. You will only be prescribed Zumenon if your symptoms seriously hinder your daily life.

Prevention of osteoporosis

After the menopause some women may develop fragile bones (osteoporosis). You should discuss all available options with your doctor.

If you are at an increased risk of fractures due to osteoporosis and other medicines are not suitable for you, you can use Zumenon to prevent osteoporosis after menopause.

2. BEFORE YOU TAKE ZUMENON

Medical history and regular check-ups

The use of HRT carries risks which need to be considered when deciding whether to start taking it, or whether to carry on taking it.

The experience in treating women with a premature menopause (due to ovarian failure or surgery) is limited. If you have a premature menopause the risks of using HRT may be different. Please talk to your doctor.

Before you start (or restart) HRT, your doctor will ask about your own and your family's medical history. Your doctor may decide to perform a physical examination. This may include an examination of your breasts and/ or an internal examination, if necessary.

Once you have started on Zumenon you should see your doctor for regular check-ups (at least once a year). At these check-ups, discuss with your doctor the benefits and risks of continuing with Zumenon.

Go for regular breast screening, as recommended by your doctor.

Do not take Zumenon

If any of the following applies to you. If you are not sure about any of the points below, **talk to your doctor** before taking Zumenon,

Do not take Zumenon

- If you have or have ever had **breast cancer**, or if you are suspected of having it
- If you have **cancer which is sensitive to oestrogens**, such as cancer of the womb lining (endometrium), or if you are suspected of having it
- If you have any **unexplained vaginal bleeding**
- If you have **excessive thickening of the womb lining** (endometrial hyperplasia) that is not being treated.
- If you have or have ever had a **blood clot in a vein** (thrombosis), such as in the legs (deep venous thrombosis) or the lungs (pulmonary embolism)
- If you have a **blood clotting disorder** (such as protein C, protein S, or antithrombin deficiency)
- If you have or recently have had a disease caused by blood clots in the arteries, such as a **heart attack, stroke** or **angina**
- If you have or have ever had a **liver disease** and your liver function tests have not returned to normal
- If you have a rare blood problem called "porphyria" which is passed down in families (inherited)
- If you are **allergic** (hypersensitive) to oestradial or any of the other ingredients of Zumenon (listed in section 6 Further information)
- if you still have your womb and are not currently taking some form of progestogen hormone

If any of the above conditions appear for the first time while taking Zumenon, stop taking it at once and consult your doctor immediately.

When to take special care with Zumenon

Tell your doctor if you have ever had any of the following problems, before you start the treatment, as these may return or become worse during treatment with Zumenon. If so, you should see your doctor more often for check-ups:

- fibroids inside your womb
- growth of womb lining outside your womb (endometriosis) or a history of excessive growth of the womb lining (endometrial hyperplasia)
- increased risk of developing blood clots (see "Blood clots in a vein (thrombosis)")
- increased risk of getting a oestrogen-sensitive cancer (such as having a mother, sister or grandmother who has had breast cancer)
- high blood pressure.
- a liver disorder, such as a benign liver tumour
- diabetes
- gallstones
- migraine or severe headaches.
- a disease of the immune system that affects many organs of the body (systemic lupus erythematosus, SLE)
- epilepsy
- asthma
- a disease affecting the eardrum and hearing (otosclerosis)
- a very high level of fat in your blood (triglycerides)
- fluid retention due to cardiac or kidney problems

Stop taking Zumenon and see a doctor immediately

If you notice any of the following when taking HRT:

- any of the conditions mentioned in the 'DO NOT take Zumenon' section
- yellowing of your skin or the whites of your eyes (jaundice). These may be signs of a liver disease
- a large rise in your blood pressure (symptoms may be headache, tiredness, dizziness).
- migraine-like headaches which happen for the first time.
- if you become pregnant
- if you notice signs of a blood clot, such as:
  - painful swelling and redness of the legs
  - sudden chest pain
  - difficulty in breathing

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

Note: Zumenon is not a contraceptive. If it is less than 12 months since your last menstrual period or you are under 50 years old, you may still need to use additional contraception to prevent pregnancy. Speak to your doctor for advice.

HRT and cancer

Excessive thickening of the lining of the womb (endometrial hyperplasia) and cancer of the lining of the womb (endometrial cancer)

Taking oestrogen-only HRT will increase the risk of excessive thickening of the lining of the womb (endometrial hyperplasia) and cancer of the womb lining (endometrial cancer).

Taking a progestogen in addition to the oestrogen for at least 12 days of each 28 day cycle protects you from this extra risk. So your doctor will prescribe a progestogen separately if you still have your womb. If you have had your womb removed (a hysterectomy), discuss with your doctor whether you can safely take this product without a progestogen.

In women who still have a womb and who are not taking HRT, on average, 5 in 1000 will be diagnosed with endometrial cancer between the ages of 50 and 65. For women aged 50 to 65 who still have a womb and who take oestrogen-only HRT, between 10 and 60 women in 1000 will be diagnosed with endometrial cancer (i.e. between 5 and 55 extra cases), depending on the dose and for how long it is taken.

Unexpected bleeding

You will have a bleed once a month (so-called withdrawal bleed) while taking Zumenon. But, if you have unexpected bleeding or drops of blood (spotting) besides your monthly bleeding, which:

- carries on for more than the first 6 months
- starts after you have been taking Zumenon more than 6 months
- carries on after you have stopped taking Zumenon

see your doctor as soon as possible

Breast cancer

Evidence suggests that taking combined oestrogen-progestogen and possibly also oestrogen-only HRT increases the risk of breast cancer. The extra risk depends on how long you take HRT. The additional risk becomes clear within a few years. However, it returns to normal within a few years (at most 5) after stopping treatment.

For women who have had their womb removed and who are using oestrogen-only HRT for 5 years, little or no increase in breast cancer risk is shown.

Women aged 50 to 79 who are not taking HRT, on average, 9 to 17 in 1000 will be diagnosed with breast cancer over a 5-year period. For women aged 50 to 79 who are taking oestrogen-progestogen HRT over 5 years, there will be 13 to 23 cases in 1000 users (i.e. an extra 4 to 6 cases).

- **Regularly check your breasts. See your doctor if you notice any changes such as:**
  - dimpling of the skin
  - changes in the nipple
  - any lumps you can see or feel

Ovarian cancer

Ovarian cancer is rare. A slightly increased risk of ovarian cancer has been reported in women taking HRT for at least 5 to 10 years.

Women aged 50 to 69 who are not taking HRT, on average about 2 women in 1000 will be diagnosed with ovarian cancer over a 5-year period. For women who have been taking HRT for 5 years, there will be between 2 and 3 cases per 1000 users (i.e. up to 1 extra case).

Effect of HRT on heart and circulation

Blood clots in a vein (thrombosis)

The risk of **blood clots in the veins** is about 1.3 to 3- times higher in HRT users than in non-users, especially during the first year of taking it.

Blood clots can be serious, and if one travels to the lungs, it can cause chest pain, breathlessness, fainting or even death.

You are more likely to get a blood clot in your veins as you get older and if any of the following applies to you. Inform your doctor if any of these situations applies to you:

- you are unable to walk for a long time because of major surgery, injury or illness (see also section 3, If you need to have surgery)
- you are seriously overweight (BMI >30 kg/m2)
- you have any blood clotting problem that needs long-term treatment with a medicine used to prevent blood clots
- if any of your close relatives has ever had a blood clot in the leg, lung or another organ
- you have systemic lupus erythematosus (SLE)
- you have cancer.

For signs of a blood clot, see "Stop taking Zumenon and see a doctor immediately".

Looking at women in their 50s who are not taking HRT, on average, over a 5-year period, 4 to 7 in 1000 would be expected to get a blood clot in a vein.

For women in their 50s who have been taking oestrogen-progestogen HRT for over 5 years, there will be 9 to 12 cases in 1000 users (i.e. an extra 5 cases).

For women in their 50s who have had their womb removed and have been taking oestrogen-only HRT for over 5 years, there will be 5 to 8 cases in 1000 users (i.e. 1 extra case).

Heart disease (heart attack)

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

Women over the age of 60 years who use oestrogen-progestogen HRT are slightly more likely to develop heart disease than those not taking any HRT.

For women who have had their womb removed and are taking oestrogen-only therapy there is no increased risk of developing a heart disease.

Stroke

The risk of getting stroke is about 1.5 times higher in HRT users than in non-users. The number of extra cases of stroke due to use of HRT will increase with age.

Looking at women in their 50s who are not taking HRT, on average, 8 in 1000 would be expected to have a stroke over a 5-year period. For women in their 50s who are taking HRT, there will be 11 cases in 1000 users, over 5 years (i.e. an extra 3 cases).

Other conditions

- HRT will not prevent memory loss. There is some evidence of a higher risk of memory loss in women who start using HRT after the age of 65. Speak to your doctor for advice.

Using other medicines

Some medicines may interfere with the effect of Zumenon. This might lead to irregular bleeding. This applies to the following medicines:

- Medicines for **epilepsy** (such as phenobarbital, phenytoin and carbamazepin)
- Medicines for **tuberculosis** (such as rifampicin, rifabutin)
- Medicines for **HIV infection** (such as nevirapine, efavirenz, ritonavir and nelfinavir)
- Herbal remedies containing **St John's Wort** (Hypericum perforatum).

Problems due to high levels of the following medicines may occur when you take Zumenon so careful drug monitoring and dose decrease may become necessary:
- tacrolimus and cyclosporin – used, for example, for organ transplants
- fentanyl – a painkiller
- theophylline – used for asthma and other breathing problems

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines obtained without a prescription, herbal medicines or other natural products.

Laboratory tests

If you need a blood test, tell your doctor or the laboratory staff that you are taking Zumenon, because this medicine can affect the results of some tests.

Pregnancy and breast-feeding

Zumenon is for use in peri and postmenopausal women only. If you become pregnant, stop taking Zumenon and contact your doctor.

Important information about some of the ingredients of Zumenon

Zumenon tablets contain milk sugar (lactose). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE ZUMENON

Always take Zumenon exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Take one tablet every day, without a break between packs. Swallow the tablet with water, with or without food.

In women with a uterus, a progestagen should normally be added to Zumenon for 12 - 14 days of each month. If you are having regular periods you should start taking Zumenon on day one of bleeding.

If you are not having regular periods and are not taking any other HRT preparations, or you are switching from a combined continuous HRT product, you can start taking Zumenon on any convenient day.

If you are currently using a 'cyclic' or 'sequential' HRT preparation (which involves taking an oestrogen tablet or patch for part of the month, followed by both oestrogen and progestagen tablet or patch for up to 14 days) start taking Zumenon the day after you finish the pack i.e. at the end of the progestagen phase.

Your doctor will aim to prescribe the lowest dose to treat your symptom for as short as necessary. Speak to your doctor if you think this dose is too strong or not strong enough.

You may experience some irregular bleeding or light bleeding (spotting) during your first few months of taking Zumenon. If the bleeding is troublesome, or continues beyond the first few months of treatment you should discuss this with your doctor.

If you take more Zumenon than you should

If you or somebody else takes too many Zumenon tablets, they are unlikely to come to any harm. Nausea (feeling sick), vomiting, sleepiness, dizziness and withdrawal bleeding may occur. No treatment is necessary, but if you are worried contact your doctor for advice.

If you forget to take Zumenon

Take the missed tablet as soon as you remember. If it is more than 12 hours since you took the last one, take the next dose without taking the forgotten tablet. Do not take a double dose. Bleeding or spotting may occur if you miss a dose.

If you need to have surgery

If you are going to have surgery, tell the surgeon that you are taking Zumenon. You may need to stop taking Zumenon about 4 to 6 weeks before the operation to reduce the risk of a blood clot (see section 2, Blood clots in a vein). Ask your doctor when you can start taking Zumenon again.

If you stop taking Zumenon

Do not stop taking Zumenon without first talking to your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist

4. POSSIBLE SIDE EFFECTS

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

The following diseases are reported more often in women using HRT compared to women not using HRT:
- breast cancer
- abnormal growth or cancer of the lining of the womb (endometrial hyperplasia or cancer)
- ovarian cancer
- blood clots in the veins of the legs or lungs (venous thromboembolism)
- heart disease
- stroke
- probable memory loss if HRT is started over the age of 65

For more information about these side effects, see Section 2.

The following serious side effects may occur during treatment with Zumenon:
- swelling of the skin around the face and neck. This may cause difficulty breathing.
- heart attack
- heavy, irregular or painful bleeds

If any of these side effects occur you should stop treatment immediately and contact your doctor.

The following side effects may occur during treatment:

Common (in less than 1 in 10, but more than 1 in 100 patients treated):
- headache
- feeling sick
- leg cramps
- abdominal pain
- pelvic pain
- unscheduled bleeding or spotting
- wind (flatulence)
- feeling weak (asthenia)
- weight changes
- rash or itching

Uncommon (in less than 1 in 100, but more than 1 in 1,000 patients treated):
- hypersensitivity (allergic) reaction such as skin rash, itching, skin redness
- hives
- painful reddish skin nodules (erythema nodosum)
- feeling down
- depression
- vaginal thrush (a vaginal infection due to a fungus called *Candida albicans*)
- symptoms of cystitis
- high blood pressure
- swelling of the ankles, feet or fingers (peripheral oedema)
- water retention (oedema)
- peripheral vascular disease
- varicose veins
- blood clots in the veins of the legs or lungs (venous thromboembolism)
- gallbladder disease
- back pain
- problems with your sight
- faster heart beat (palpitations)
- breast pain or tenderness
- indigestion
- nervousness
- dizziness
- fibroids get bigger (growths in the womb increase)
- changes in the cervix (the lower end of the womb)

Rare (in less than 1 in 1,000, but more than 1 in 10,000 patients treated):
- liver disorders, which may include jaundice (yellowing of the skin), asthenia (feeling weak) or general malaise, and abdominal pain
- change in the surface of the eye
- intolerance to contact lenses
- pre-menstrual tension (PMT)
- feeling anxious
- migraine
- vomiting
- feeling bloated
- excessive hair growth
- acne
- muscle cramps
- vaginal discharge
- feeling tired
- swelling of the breasts
- change in sex drive

Very rare (in less than 1 in 10,000 patients treated, not known (cannot be estimated from the available data)):
- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness (anaemia)
- chorea (muscle twitches)
- skin discolouration (purpura)
- worsening of porphyria (a metabolic disease)
- stroke
- rash with target-shaped reddening or sores (erythema multiforme)
- discoloration of the skin especially of the face or neck known as "pregnancy patches" (chloasma or melasma)

If unscheduled bleeding occurs after some time on HRT, you should contact your doctor. If unscheduled bleeding continues after stopping HRT, it may be necessary to perform tests to exclude disease of the endometrium (the lining of the uterus).

Changes can occur in the levels of certain proteins and hormones in the blood. The action of the hormones in the body is not affected. You should tell your doctor that you are taking HRT if you are to have a blood test.

The following side effects have been reported with other HRTs:
- a disease where the immune system abnormally attacks many organs of the body (systemic lupus erythematosus)
- change in metabolism of sugars and starches (carbohydrate)
- high levels of certain blood fats (hypertriglyceridemia)
- worsening of fits (epilepsy)
- blood clots in the arteries (arterial thromboembolism)
- inflammation of the pancreas (pancreatitis) in women with pre-existing high levels of certain blood fats (hypertriglyceridemia)
- a condition where gastric juices, containing acid, travel back from the stomach into the oesophagus (gastrooesophageal reflux disease) symptoms include heartburn
- urinary incontinence
- painful/lumpy breasts (fibrocystic breast disease)
- increased total thyroid hormones

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ZUMENON

Keep out of the reach and sight of children.

Do not store above 30°C.

Do not use Zumenon after the "use before" date which is stated on the pack. The "use before" date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Zumenon contains

- The active substance is oestradiol (as hemihydrate)

Each tablet contains 2 mg oestradiol hemihydrate.

The other ingredients in the tablet core are:
- lactose
- hypromellose
- maize starch
- colloidal anhydrous silica
- magnesium stearate

The other ingredients in the film coating are:
- hypromellose
- talc
- macrogol 400
- titanium dioxide (E171)
- red, black and yellow iron oxides (E172)

What Zumenon looks like and contents of the pack

Brick-red, round film-coated tablets.

The inscription on the tablets is 379 on one side.

The tablets are packed in a PVC film with a covering aluminium foil.

The blister strips contain 28 film-coated tablets. There are 84 tablets in each carton.

Marketing Authorisation Holder

Abbott Healthcare Products Ltd
Abbott House,
Vanwall Business Park,
Vanwall Road, Maidenhead,
SL6 4XE,
UK

Manufacturer

Abbott Biologicals BV
8121 AA, Olst
The Netherlands

This leaflet was last revised in January 2015.

For information in large print, tape, CD or Braille, phone 02380 467000 (UK)

Abbott

1096408