

Package leaflet: Information for the user

Veozza 45 mg film-coated tablets fezolinetant

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Veozza is and what it is used for
2. What you need to know before you take Veozza
3. How to take Veozza
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1. What Veozza is and what it is used for

Veozza contains the active substance fezolinetant. Veozza is a non-hormonal medicine used in menopausal women to reduce moderate-to-severe vasomotor symptoms (VMS) associated with menopause. VMS are also known as hot flashes or night sweats.

Before menopause, there is a balance between oestrogens, a female sex hormone, and a protein made by the brain known as neurokinin B (NKB) that regulates your brain's temperature control centre. As your body goes through menopause, oestrogen levels decline and this balance is disrupted, which can lead to VMS. By blocking NKB binding in your temperature control centre, Veozza reduces the number and intensity of hot flashes and night sweats.

2. What you need to know before you take Veozza

Do not take Veozza

- if you are allergic to fezolinetant or any of the other ingredients of this medicine (listed in section 6).
- with medicines known as moderate or strong CYP1A2 inhibitors (e.g., ethinyl oestradiol containing contraceptives, mexiletine, enoxacin, fluvoxamine). These medicines can reduce the breakdown of Veozza in the body, leading to more side effects. See 'Other medicines and Veozza' below.
- if you are pregnant or think you may be pregnant.

Warnings and precautions

Before you start taking Veoza you will have a blood sample taken to check your liver function. This check should be repeated monthly during the first three months of treatment and at regular intervals afterwards if required by your doctor.

Talk to your doctor or pharmacist before taking Veoza

- your doctor may ask for your full medical history, including family history.
- if you have ongoing liver disease or liver problems.
- if you have kidney problems. Your doctor may not prescribe this medicine to you.
- if you currently have or previously had breast cancer or another oestrogen-related cancer. During treatment, your doctor may not prescribe this medicine to you.
- if you are taking hormone replacement therapy with oestrogens (medicines used to treat oestrogen deficiency symptoms). Your doctor may not prescribe this medicine to you.
- if you have a history of seizures. Your doctor may not prescribe this medicine to you.

Tell your doctor immediately if you get any of the following signs and symptoms during treatment with Veoza:

- **if you notice any sign or symptom of a liver problem.**

The list of associated symptoms is provided in section 4. Possible side effects.

Children and adolescents

Do not give this medicine to children and adolescents under 18 years of age, because this medicine is only for menopausal women.

Other medicines and Veoza

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines without a prescription.

Certain medicines may increase the risk of side effects of Veoza by increasing the amount of Veoza in the blood. These medicines must not be taken while you are taking Veoza, and include:

- Fluvoxamine (a medicine used to treat depression and anxiety)
- Enoxacin (a medicine used to treat infections)
- Mexiletine (a medicine used to treat symptoms of muscle stiffness)
- Ethinyl oestradiol containing contraceptives (medicines used to prevent pregnancy)

Pregnancy and breast-feeding

Do not take this medicine if you are pregnant or breast-feeding, or if you think you might be pregnant. This medicine is for use only by menopausal women. If you become pregnant while taking this medicine, stop taking it immediately and talk to your doctor. Women of childbearing potential should use effective non-hormonal contraception.

Driving and using machines

Veoza has no effect on the ability to drive or use machines.

3. How to take Veoza

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one 45 mg tablet taken by mouth once daily.

Instructions for proper use

- Take this medicine at about the same time each day.
- Swallow the tablet whole with liquids. Do not break, crush, or chew the tablet.
- Take with or without food.

If you take more Veoza than you should

If you have taken more tablets than you have been told to take, or if someone else accidentally takes your tablets, contact your doctor or pharmacist straight away.

Symptoms of overdose may include headache, feeling sick (nausea), or a tingling or prickling sensation (paraesthesia).

If you forget to take Veoza

If you forget to take your medicine, take the missed dose as soon as you remember on the same day, and at least 12 hours before the next scheduled dose. If there is less than 12 hours before the next scheduled dose, do not take the missed dose. Return to your regular schedule the following day. Do not take a double dose to make up for a forgotten individual dose.

If you miss several doses, tell your doctor and follow the advice given to you.

If you stop taking Veoza

Do not stop taking this medicine unless your doctor tells you to do so. If you decide to stop taking this medicine before finishing the prescribed course of treatment, you should talk to your doctor first.

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

4. Possible side effects

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

Some side effects (e.g. liver injury) could be serious.

If you experience any of the following side effects, tell your doctor immediately:

- tiredness, itching skin, yellowing of the skin and eyes, dark urine, light-coloured stools, feeling sick (nausea or vomiting), loss of appetite, and/or stomach ache. These symptoms may be signs of liver injury (frequency not known, since it cannot be estimated from the available data).

Common (may affect up to 1 in 10 people)

- diarrhoea
- difficulty sleeping (insomnia)
- increase in levels of certain liver enzymes (ALT or AST), as shown in blood tests
- stomach (abdominal) pain

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Veoza

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Veoza contains

- The active substance is fezolinetant. Each film-coated tablet contains 45 mg of fezolinetant.
- The other ingredients are:
Tablet core: mannitol (E421), hydroxypropyl cellulose (E463), low-substituted hydroxypropyl cellulose (E463a), microcrystalline cellulose (E460), magnesium stearate (E470b).
Film-coating: hypromellose (E464), talc (E553b), macrogol (E1521), titanium dioxide (E171), iron oxide red (E172).

What Veoza looks like and contents of the pack

Veoza 45 mg tablets are round, light red, film-coated tablets (tablets) debossed with the company logo and '645' on the same side.

Veoza is available in PA/Aluminium/PVC/Aluminium unit dose blisters in cartons.

Pack sizes: 28 × 1, 30 × 1, and 100 × 1 film-coated tablets.

Not all pack sizes may be marketed.

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