

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a doctor's prescription only

**Veozza 45 mg
film-coated tablets**

Composition:

Each film-coated tablet contains 45 mg of fezolinetant.

Inactive ingredients and allergens - see section 6 'Further information'.

Read this leaflet carefully in its entirety before using the medicine.

This leaflet contains concise information about the medicine. If you have further questions, consult your doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Veozza is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.

Therapeutic group: Other gynecologicals.

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. BEFORE USING THE MEDICINE

Do not use the medicine:

- if you are sensitive (allergic) to fezolinetant or any of the other ingredients of this medicine (see section 6 'Further information').
- with medicines known as moderate or strong CYP1A2 inhibitors (e.g., ethinyl oestradiol containing contraceptives, mexiletine, enoxacin, fluvoxamine). see section 'Drug interactions' below.
- if you are pregnant or think you may be pregnant.
- if you have moderate or severe liver failure.

Warnings and precautions:

Talk to your doctor or pharmacist before taking Veozza:

- your doctor may ask for your full medical history, including family history.
- it is not recommended to take Veozza if you have mild liver failure. Your doctor may prescribe you with this medicine and will monitor your liver enzymes.

- 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.

Children and adolescents:

Veozza is not intended for use by children and adolescents under 18 years of age, because this medicine is intended for use by menopausal women only.

Tests and follow-up

Your doctor will ask you to perform blood tests to monitor your liver function before beginning of treatment and during the first 3 months of treatment with Veozza.

During treatment period, your doctor may ask for liver tests.

Drug Interactions:

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

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

Use of the medicine and food

The medicine may be taken with or without food.

Pregnancy, breastfeeding and fertility:

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:

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

3. HOW SHOULD YOU TAKE THE MEDICINE?

Liver function should be checked before and during the first three months of treatment.

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

The dosage and treatment regimen will be determined by your doctor only. The recommended dose is one 45 mg tablet taken by mouth once daily.

Treatment duration

The benefit of long-term treatment should be periodically evaluated because the duration of vasomotor symptoms associated with menopause (VMS) can change over time.

Do not exceed the recommended dose.

Direction for 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.

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 or proceed to a hospital emergency room and bring the package of the medicine with you.

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.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

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

4. SIDE EFFECTS

As with any medicine, use of Veoza may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

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

If you get any side effects, if any of the side effects worsen, or if you are suffering from a side effect not mentioned in the leaflet, consult your doctor.

Reporting of side effects:

Side effects may be reported to the Ministry of Health by clicking on the link “report side effects due to medicinal treatment” found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il>.

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning.
Do not induce vomiting without an explicit instruction from your doctor.

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.
It is recommended to store the medicine in room temperature.

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. FURTHER INFORMATION

In addition to the active ingredients, the medicine also contains:

Tablet core: mannitol (E421), microcrystalline cellulose (E460), low-substituted hydroxypropyl cellulose (E463a), hydroxypropyl cellulose (E463), magnesium stearate (E470b).

Film-coating: hypromellose (E464), talc (E553b), macrogol (E1521), titanium dioxide (E171), iron oxide red (E172).

What Veoza looks like and the contents of the package:

Veoza 45 mg tablets are round, light red, film-coated tablets (tablets), approximately 7.1 mm diameter, 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: 30 × 1 film-coated tablets.

License holder and address:

Astellas Pharma International B.V., 21 Ha'melacha Street, Rosh Ha'ayin, 4809157, Israel.

Manufacturer and address:

Astellas Pharma Europe B.V.
Sylviusweg 62, 2333 BE Leiden, The Netherlands

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Veoza 45mg 30 film coated tablets: 176-65-37787-99

Approved in 06.2024