**SCHEDULING STATUS: S4**

**Veoza™ 45 mg film-coated tablets**

**Fezolinetant**

**Sugar free**

**Read all of this leaflet carefully before you start taking Veoza 45 mg 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, pharmacist, nurse or other health care provider.
- Veoza 45 mg has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms 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 Veoza 45 mg is and what it is used for

Veoza 45 mg contains the active substance fezolinetant. Veoza 45 mg 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, hot flushes 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, Veoza 45 mg reduces the number and intensity of hot flashes and night sweats.

## 2. What you need to know before you take Veoza 45 mg

**Do not take Veoza 45 mg**

- if you are allergic to Veoza 45 mg 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 Veoza 45 mg in the body, leading to more side effects. See 'Other medicines and Veoza 45 mg' below.
- if you are pregnant or think you may be pregnant.

**Warnings and precautions**

Before you start taking Veoza 45 mg 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 health care provider before taking Veoza 45 mg

- your doctor may ask for your full medical history, including family history.
- if you have ongoing liver disease or liver problems. Your doctor will monitor your liver enzymes as noted above.
- 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 45 mg:**

- **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 Veoza 45 mg to children and adolescents under 18 years of age, because this medicine is only for menopausal women.

**Other medicines and Veoza 45 mg**

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Certain medicines may increase the risk of side effects of Veoza 45 mg by increasing the amount of Veoza 45 mg in the blood. These medicines must not be taken while you are taking Veoza 45 mg, 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, breast-feeding 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**

Veoza 45 mg has no effect on the ability to drive or use machines.

Veoza 45 mg contains

Mannitol, a sugar.

## 3. How to take Veoza 45 mg

Do not share medicines prescribed for you with any other person.

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 45 mg than you should**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

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

### If you forget to take Veoza 45 mg

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 45 mg

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

Veoza 45 mg can have side effects. Not all side effects reported for Veoza 45 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Veoza 45 mg, please consult your health care provider for advice.

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

**Not known**

- Drug-induced liver injury

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website

And

Astellas Pharma (Pty) Ltd., 7 Mirage Road, Bedfordview, 2007, South Africa

Tel: +27 11 615 9433

Mobile: +27 82 410 8864

Email: drugsafety.za@astellas.com

By reporting side effects, you can help provide more information on the safety of Veoza 45 mg.

## 5. How to store Veoza 45 mg

Store all medicines out of 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.

Store at or below 25°C

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 protect the environment.

## 6. Contents of the pack and other information

### What Veoza 45 mg 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).

  Sugar free.

### What Veoza 45 mg 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 45 mg is available in PA/Aluminium/PVC/Aluminium unit dose blisters in cartons.
Pack sizes: 28 x 1, 30 x 1, and 100 x 1 film-coated tablets.

Not all pack sizes may be marketed.

### Holder of Certificate of Registration

Astellas Pharma (Pty) Ltd., 7 Mirage Road, Bedfordview, 2007, South Africa

## This leaflet was last revised in

23 June 2026

## Registration number

A 59/21.13/0510