

# Veoz<sup>TM</sup> film-coated tablets

Fezolinetant (45 mg)

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### 1. What Veoz is used for

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

### 2. How Veoz works

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. During menopause, oestrogen levels decline and this balance is disrupted, which can lead to VMS. By blocking NKB binding in your temperature control centre, Veoz reduces the number and intensity of hot flashes and night sweats.

### 3. Before you use Veoz

#### - When you must not use it

- if you are allergic to fezolinetant or any of the other ingredients of Veoz (listed in section 8).
- 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 Veoz in the body, leading to more side effects. See '**5. While you are using it** Things you must not do'.

#### - Before you start to use it

Before you start taking Veoz 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 Veoz

- 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 Veoz 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.

#### - Taking other medicines

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

### 4. How to use Veoz

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

- Swallow the tablet whole with liquids. Do not break, crush, or chew the tablet.
- Take with or without food.

#### - How much to use

Your doctor will tell you what dose of Veoz to take. The recommended dose is one 45 mg tablet taken by mouth once daily.

#### - When to use it

Take Veoz at about the same time each day.

#### - How long to use it

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

#### - If you forget to use it

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 use too much (overdose)

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.

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

### 5. While you are using it

#### - Things you must not do

- Do not give Veoz to children and adolescents under 18 years of age, because Veoz is only for menopausal women.
- Certain medicines may increase the risk of side effects of Veoz by increasing the amount of Veoz in the blood. These medicines must not be taken while you are taking Veoz, and include:
  - Fluvoxamine (a medicine used to treat depression and anxiety)
  - Enoxacin (a medicine used to treat infections)

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- Mexiletine (a medicine used to treat symptoms of muscle stiffness)
- Ethinyl oestradiol containing contraceptives (medicines used to prevent pregnancy)

*- Things to be careful of*

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

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

The list of associated symptoms is provided in '6. Side effects'.

*Pregnancy and breast-feeding*

Veoz is for use only by menopausal women. If you become pregnant while taking Veoz, immediately talk to your doctor.

*Driving and using machines*

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

## 6. 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:

**Frequency not known** (cannot be estimated from the available data)

- tiredness
- itching skin
- yellowing of the skin and eyes
- dark urine
- light-coloured stools
- feeling sick (nausea or vomiting)
- loss of appetite
- stomach ache

**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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

## 7. Storage and Disposal of Veoz

### - *Storage*

Keep Veoz out of the sight and reach of children.

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

Do not store above 30°C.

Store in the original package in order to protect from moisture and humidity.

### - *Disposal*

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.

## 8. Product Description

### - *What it looks like*

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

The tablets are provided in blisters and are available in packs containing 10 film-coated tablets (1-blisters of 10 film-coated tablets) or 30 film-coated tablets (3-blisters of 10 film-coated tablets). Not all pack sizes may be marketed.

### - *Ingredients*

- The active substance is fezolinetant. Each film-coated tablet contains 45 mg of fezolinetant.

- **Tablet core:** mannitol, hydroxypropyl cellulose, low-substituted hydroxypropyl cellulose, microcrystalline cellulose, magnesium stearate.
- **Film-coating:** hypromellose, talc, polyethylene glycol (macrogol), titanium dioxide, ferric oxide (iron oxide red).

### - *MAL number*

MALXXXXXXXXXARZ

## 9. Manufacturer and Product Registration Holder

### Manufacturer

Astellas Pharma Inc.  
Yaizu Technology Center  
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### Product Registration Holder

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## 10. Date of revision

01 Aug 2025

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