VEOZA™

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I using VEOZA?

VEOZA contains the active substance fezolinetant. VEOZA is not a hormone. This medicine is used in menopausal women to reduce moderate to severe vasomotor symptoms (VMS), associated with menopause. VMS are also known as hot flushes or night sweats.

For more information, see Section 1. Why am I using VEOZA? in the full CMI.

2. What should I know before I use VEOZA?

Talk to your doctor if you have any other medical conditions or if you take any other medicines.

For more information, see Section 2. What should I know before I use VEOZA? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with VEOZA and affect how it works.

For more information, see Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use VEOZA?

The recommended dose is one tablet by mouth once daily.

More instructions can be found in Section 4. How do I use VEOZA? in the full CMI.

5. What should I know while using VEOZA?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using VEOZA.
Things you should not do	• Do not stop taking this medicine unless your doctor tells you to do so.
Driving or using machines	• VEOZA has no effect on the ability to drive or use machines.
Looking after your medicine	• Store below 30°C.

For more information, see Section 5. What should I know while using VEOZA? in the full CMI.

6. Are there any side effects?

There are side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details). The most common side effects are diarrhoea, difficulty sleeping (insomnia), increased liver laboratory values and abdominal pain.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

VEOZA™

Active ingredient(s): *fezolinetant*

Consumer Medicine Information (CMI)

This leaflet provides important information about using VEOZA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using VEOZA.**

Where to find information in this leaflet:

1. Why am I using VEOZA?
2. What should I know before I use VEOZA?
3. What if I am taking other medicines?
4. How do I use VEOZA?
5. What should I know while using VEOZA?
6. Are there any side effects?
7. Product details

1. Why am I using VEOZA?

VEOZA contains the active substance fezolinetant.

VEOZA is not a hormone.

This medicine is used in menopausal women to reduce moderate to severe vasomotor symptoms (VMS), associated with menopause. VMS are also known as hot flushes or night sweats.

Before menopause, there is a balance between oestrogen, a female sex hormone, and a brain chemical known as neurokinin B (NKB) that regulates your body's temperature control center located in a specific area of the brain. As your body goes through menopause, oestrogen declines and this balance is disrupted, which can lead to hot flushes and night sweats, also known as VMS. VEOZA helps to restore the balance by blocking NKB in your temperature control center to reduce the number and intensity of hot flushes. VEOZA is a non-hormonal medicine.

2. What should I know before I use VEOZA?

Warnings

Do not use VEOZA if:

- you are allergic to fezolinetant, or any of the ingredients listed at the end of this leaflet.
- you are taking certain 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 in the body, leading to more side effects.
- you have moderate or severe liver dysfunction.
- you have severe kidney dysfunction.
- Always check the ingredients to make sure you can use this medicine.

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 3 months, at 6 months, and 9 months after treatment initiation and at regular intervals afterwards, if required by your doctor.

Check with your doctor when:

- take any medicines for any other condition.
- have any other medical conditions.
- currently have or previously had breast cancer or another oestrogen-related cancer. During treatment, your doctor may not prescribe this medicine to you.
- are taking hormone replacement therapy with oestrogens (medicines used to treat oestrogen deficiency symptoms). Your doctor may not prescribe this medicine to you.
- have kidney problems. Your doctor may not prescribe this medicine to you.

Tell your doctor immediately if you notice the following signs or symptoms of liver problems during treatment with VEOZA.

The associated signs or symptoms are listed in Section 6. Are there any side effects?.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

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.

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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

VEOZA may affect the way these medicines work, or these medicines may affect how VEOZA works. This includes

medicines known to moderately and strongly reduce the activity of an enzyme (called cytochrome P450 1A2), such as fluvoxamine. If you normally take any of these medicines, your doctor might change it and prescribe a different medicine for you during your treatment with VEOZA.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect VEOZA.

4. How do I use 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.

How much to take

The recommended dose is one tablet by mouth once daily.

When to take VEOZA

- Take this medicine at about the same time each day.

How to take VEOZA

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

If you forget to take VEOZA

VEOZA should be used regularly at the same time each day. If you miss your dose at the usual time, take the missed dose as soon as you remember on the same day, with at least 12 hours before the next scheduled dose. Return to your regular schedule the following day.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

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

If you take too much VEOZA

If you think that you have used too much VEOZA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using VEOZA?

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking VEOZA.

If you are going to have surgery, tell the surgeon or anesthetist that you are taking this medicine.

Keep all of your doctor's appointments so that your progress can be checked. Remind any doctor, dentist or pharmacist you visit that you are using VEOZA.

Things you should not do

- Do not stop using this medicine suddenly.

Driving or using machines

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

Be careful before you drive or use any machines or tools until you know how VEOZA affects you.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place where the temperature stays below 30°C and away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• diarrhoea • difficulty sleeping (insomnia) • pain in the right upper stomach (abdomen) abdominal pain • headache • runny nose, sneezing, and coughing • feeling sick • sleepiness • joint pain • back pain • urinary tract infection • abnormal vaginal bleeding	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• **signs and symptoms of liver injury - tiredness, itching skin, nausea, vomiting, yellowing of the eyes or skin (jaundice), dark urine, light-coloured stools, loss of appetite, and/or stomach ache**	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What VEOZA contains

Active ingredient (main ingredient)	fezolinetant
Other ingredients (inactive ingredients)	mannitol hyprolose microcrystalline cellulose magnesium stearate hypromellose purified talc macrogol 8000 titanium dioxide ferric oxide (iron oxide red)

Do not take this medicine if you are allergic to any of these ingredients.

What VEOZA looks like

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

(AUST R 401401).

Who distributes VEOZA

VEOZA is supplied in Australia by:

Astellas Pharma Australia Pty Ltd

Suite 2.01, 2 Banfield Road

Macquarie Park NSW 2113

Medical Information:

1800 751 755

VEOZA™ is a trademark of Astellas US LLC.

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