

PATIENT INFORMATION

VEOZAH® (vee-O-zah)
(fezolinetant)
tablets, for oral use

What is the most important information I should know about VEOZAH?

VEOZAH can cause serious side effects, including:

- **Liver Problems.** Your healthcare provider will do a blood test to check your liver before you start taking VEOZAH. Your healthcare provider will also do this blood test monthly for the first 3 months, at month 6, and month 9 after you start taking VEOZAH or if you have signs or symptoms that suggest liver problems. If your liver blood test values are elevated, your healthcare provider may advise you to stop treatment or request additional liver blood tests.

Stop VEOZAH right away and call your healthcare provider if you have the following signs or symptoms of liver problems:

- feeling more tired than you do usually
- decreased appetite
- nausea
- vomiting
- itching
- yellowing of the eyes or skin (jaundice)
- pale feces
- dark urine
- pain in the stomach (abdomen)

See “What are the possible side effects of VEOZAH?” for more information about side effects.

What is VEOZAH?

VEOZAH is a prescription medicine used to reduce moderate to severe vasomotor symptoms due to menopause. VEOZAH is not a hormone. Vasomotor symptoms are the feelings of warmth in the face, neck, and chest, or sudden intense feelings of heat and sweating (“hot flashes” or “hot flushes”).

Do not use VEOZAH if you:

- have cirrhosis.
- have severe kidney problems or kidney failure.
- are taking certain medicines called CYP1A2 inhibitors. Ask your healthcare provider if you are not sure.

Before you use VEOZAH, tell your healthcare provider about all of your medical conditions, including if you:

- have liver disease or liver problems.
- have kidney problems.
- have any medical conditions that may become worse while you are using VEOZAH.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. VEOZAH may affect the way other medicines work, and other medicines may affect how VEOZAH works. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I take VEOZAH?

- Take VEOZAH exactly as your healthcare provider tells you to take it.
- Take 1 VEOZAH tablet by mouth with or without food at about the same time each day.
- Swallow the VEOZAH tablet whole with liquid. Do not cut, crush, or chew the tablet.
- If you miss a dose of VEOZAH, take the missed dose as soon as possible on the same day, with at least 12 hours before the next scheduled dose. Return to your normal schedule the following day.

What are the possible side effects of VEOZAH?

VEOZAH can cause serious side effects, including:

- See “What is the most important information I should know about VEOZAH?”

Common side effects of VEOZAH include:

- stomach (abdominal) pain
- diarrhea
- difficulty sleeping (insomnia)
- back pain
- hot flashes or hot flushes

Tell your healthcare provider if you have any side effect that bothers you or does not go away.

These are not all the possible side effects of VEOZAH.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store VEOZAH?

- Store VEOZAH at room temperature between 68°F to 77°F (20°C to 25°C).
- Dispose of the unused medicine through a take-back option, if available. See www.fda.gov/drugdisposal for more information.
- **Keep VEOZAH and all medicines out of the reach of children.**

General information about the safe and effective use of VEOZAH.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use VEOZAH for a condition for which it was not prescribed. Do not give VEOZAH to other people, even if they have the same symptoms you have. It may harm them.

This Patient Information leaflet summarizes the most important information about VEOZAH. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about VEOZAH that is written for healthcare professionals.

What are the ingredients in VEOZAH?

Active ingredient: fezolinetant

Inactive ingredients: ferric oxide, hydroxypropyl cellulose, hypromellose, low-substituted hydroxypropyl cellulose, magnesium stearate, mannitol, microcrystalline cellulose, polyethylene glycol, talc, and titanium dioxide

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For more information, go to www.VEOZAH.com or call 1-800-727-7003.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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