PATIENT INFORMATION JOURNAVX (jor na vix) (suzetrigine) tablets, for oral use

What is JOURNAVX?

JOURNAVX is a prescription medicine used to treat adults with moderate to severe short-term (acute) pain. It is not known if JOURNAVX is safe and effective in children.

Do not take JOURNAVX if you take certain medicines that are strong inhibitors of an enzyme called CYP3A. Ask your healthcare provider if you are not sure.

Before taking JOURNAVX, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems. People with liver problems may have an increased risk of getting side effects from taking JOURNAVX.
- are pregnant or plan to become pregnant. It is not known if JOURNAVX will harm your unborn baby. You and your healthcare provider should decide if you will take JOURNAVX while you are pregnant.
- are breastfeeding or planning to breastfeed. It is not known if JOURNAVX passes into your breast milk. You and your healthcare provider should decide if you will take JOURNAVX while you are breastfeeding.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Taking JOURNAVX with certain other medicines may affect the way JOURNAVX and the other medicines work and may increase your risk of side effects. See "**Do not take JOURNAVX**". Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure.

Especially tell your healthcare provider if you take:

- hormonal birth control (contraceptives) containing progestins other than levonorgestrel or norethindrone. If you take
 one of these contraceptives (progestins other than levonorgestrel or norethindrone), they may not work as well
 during treatment with JOURNAVX. You should also use nonhormonal contraceptives such as condoms or use other
 forms of hormonal birth control during treatment with JOURNAVX and for 28 days after you stop taking JOURNAVX.
- medicines that are substrates of the CYP3A enzyme since they may become less effective during treatment with JOURNAVX. Your healthcare provider may need to adjust the dose of your medicine when starting or stopping JOURNAVX.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take JOURNAVX?

- Take JOURNAVX by mouth exactly as your healthcare provider tells you to take it.
- Swallow JOURNAVX tablets whole. Do not chew or crush the tablets.
- For your first dose of JOURNAVX:
 - Take 2 JOURNAVX tablets on an empty stomach.
 - Take your **first dose of JOURNAVX** at least 1 hour before or 2 hours after food. During this time, you may drink clear liquids, such as water, apple juice, vegetable broth, tea, or black coffee.
- After your first dose of JOURNAVX:
 - o Take 1 JOURNAVX tablet 12 hours later, with or without food.
 - o Continue to take 1 JOURNAVX tablet every 12 hours as directed by your healthcare provider.
- Take JOURNAVX for the shortest time needed.
- If you have liver problems or take certain other medicines, your dosing schedule may be different.
- If you miss a dose of JOURNAVX and do not have liver problems or take certain other medicines:
 - **Take the missed dose** as soon as possible, then take your next scheduled dose at your recommended time.
 - If you miss 2 or more doses of JOURNAVX, take 2 JOURNAVX tablets, then take your next scheduled dose at your recommended time.
- If you miss a dose of JOURNAVX and you have liver problems or are taking moderate inhibitors of an enzyme called CYP3A:
 - Take the missed dose as soon as possible.
 - If you took the missed dose and your next scheduled dose is within 6 hours, skip that dose and take your next scheduled dose at your recommended time.
- If you are not sure about your dosing, ask your healthcare provider or pharmacist.

 If you take too much JOURNAVX, call your healthcare provider or Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

What should I avoid while taking JOURNAVX?

• Do not take food or drink containing grapefruit during treatment with JOURNAVX.

What are possible side effects of JOURNAVX?

The most common side effects of JOURNAVX include:

- itching
- muscle spasms
- increased blood level of creatine phosphokinase
- rash

JOURNAVX may temporarily reduce the chance of females becoming pregnant while on treatment. Talk to your healthcare provider if you have concerns about becoming pregnant. If you are using contraceptives, you should continue to use contraceptives during treatment with JOURNAVX.

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

These are not all of the possible side effects of JOURNAVX.

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 JOURNAVX?

Store JOURNAVX at room temperature between 68°F to 77°F (20°C to 25°C).

Keep JOURNAVX and all medicines out of the reach of children.

General information about the safe and effective use of JOURNAVX.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. Do not use JOURNAVX for a condition for which it was not prescribed. Do not give JOURNAVX to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about JOURNAVX that is written for health professionals.

What are the ingredients in JOURNAVX?

Active ingredient: suzetrigine

Inactive ingredients: croscarmellose sodium, hypromellose acetate succinate, magnesium stearate, and microcrystalline cellulose. The tablet film coat contains FD&C Blue #2 aluminum lake, polyethylene glycol, polyvinyl alcohol-partially hydrolyzed, talc, and titanium dioxide.

Manufactured for: Vertex Pharmaceuticals Incorporated; 50 Northern Avenue, Boston, MA 02210



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

Issued: 01/2025