

PATIENT INFORMATION

UPTRAVI® (up-TRA-vee) (selexipag) tablets

Read this Patient Information before you start taking UPTRAVI and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is UPTRAVI?

- UPTRAVI is a prescription medicine used to treat pulmonary arterial hypertension (PAH) which is high blood pressure in the arteries of your lungs.
 - UPTRAVI can help slow down the progression of your disease and lower your risk of being hospitalized for PAH.
- It is not known if UPTRAVI is safe and effective in children.

Who should not take UPTRAVI?

Do not take UPTRAVI if you

Take gemfibrozil because this medicine may affect how UPTRAVI works and cause side effects.

What should I tell my healthcare provider before taking UPTRAVI?

Before you take UPTRAVI, tell your healthcare provider if you:

- have liver problems.
- have narrowing of the pulmonary veins, a condition called pulmonary veno-occlusive disease.
- are pregnant or plan to become pregnant. It is not known if UPTRAVI will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if UPTRAVI passes into your breast milk. You and your healthcare provider should decide if you will take UPTRAVI or breastfeed. You should not do both.
- have any other medical conditions

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. UPTRAVI and other medicines may affect each other causing side effects. Do not start any new medicine until you check with your healthcare provider.

How should I take UPTRAVI?

- Take UPTRAVI exactly as your healthcare provider tells you to take it. Do not stop taking UPTRAVI unless your healthcare provider tells you to stop.
- Your healthcare provider will slowly increase your dose to find the dose of UPTRAVI that is right for you.
- If you have side effects, your healthcare provider may tell you to change your dose of UPTRAVI.
- UPTRAVI can be taken with or without food. Taking UPTRAVI with food may help you tolerate UPTRAVI better.
- UPTRAVI is usually taken 2 times each day.
- Swallow UPTRAVI tablets whole. Do not split, crush or chew UPTRAVI tablets.
- If you miss a dose of UPTRAVI, take it as soon as you remember. If your next scheduled dose is due within 6 hours, skip the missed dose. Take the next dose at your regular time.
- If you miss 3 or more days of UPTRAVI, call your healthcare provider to see if your dose needs to be changed.
- If you take too much UPTRAVI, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of UPTRAVI?

The most common side effects of UPTRAVI include:

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|------------------------|----------------------------|
| • headache | • diarrhea |
| • jaw pain | • nausea |
| • muscle pain | • vomiting |
| • pain in arms or legs | • flushing |
| • pain in joints | • low red blood cell count |
| • decreased appetite | • rash |

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

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 UPTRAVI?

- Store UPTRAVI tablets at room temperature between 68°F and 77°F (20°C and 25°C).
- Keep UPTRAVI and all medicines out of the reach of children.

General information about the safe and effective use of UPTRAVI

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

What are the ingredients in UPTRAVI?

Active ingredient: selexipag

Inactive ingredients: corn starch, D-mannitol, hydroxypropyl cellulose, low substituted hydroxypropyl cellulose, and magnesium stearate. The tablets are film coated with a coating material containing carnauba wax, hypromellose, propylene glycol, titanium dioxide, along with mixtures of iron oxide black, iron oxide red, or iron oxide yellow.

Manufactured for:
Actelion Pharmaceutical US, Inc.
a Janssen Pharmaceutical Company
South San Francisco, CA 94080, USA

Made in the UK

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For more information, contact Janssen at 1-800-526-7736 (1-800-JANSSEN) or go to www.UPTRAVI.com.

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

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