

Patient Information
VOSEVI® (voh-SEV-ee)

(sofosbuvir, velpatasvir, and voxilaprevir) tablets

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

VOSEVI can cause serious side effects, including,

Hepatitis B virus reactivation: Before starting treatment with VOSEVI, your healthcare provider will do blood tests to check for hepatitis B virus infection. If you have ever had hepatitis B virus infection, the hepatitis B virus could become active again during or after treatment of hepatitis C virus with VOSEVI. Hepatitis B virus becoming active again (called reactivation) may cause serious liver problems including liver failure and death. Your healthcare provider will monitor you if you are at risk for hepatitis B virus reactivation during treatment and after you stop taking VOSEVI.

For more information about side effects, see the section “What are the possible side effects of VOSEVI?”

What is VOSEVI?

VOSEVI is a prescription medicine used to treat adults with chronic (lasting a long time) hepatitis C virus (HCV) infection without cirrhosis or with compensated cirrhosis who have:

- genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor.
- genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor.

It is not known if VOSEVI is safe and effective in children.

Do not take VOSEVI: if you also take any medicines that contain rifampin (Rifater®[®], Rifamate®[®], Rimactane®[®], Rifadin®[®])

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

- have ever had hepatitis B infection
- have liver problems other than hepatitis C infection
- are pregnant or plan to become pregnant. It is not known if VOSEVI will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if VOSEVI passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take VOSEVI.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. VOSEVI and other medicines may affect each other. This can cause you to have too much or not enough VOSEVI or other medicines in your body. This may affect the way VOSEVI or your other medicines work or may cause side effects.

Keep a list of your medicines to show your healthcare provider and pharmacist.

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with VOSEVI.
- **Do not start taking a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take VOSEVI with other medicines.

How should I take VOSEVI?

- Take VOSEVI exactly as your healthcare provider tells you. Do not change your dose unless your healthcare provider tells you to.
- Do not stop taking VOSEVI without first talking with your healthcare provider.
- Take 1 VOSEVI tablet by mouth each day on a regular schedule.
- Take VOSEVI with food.
- If you need to take an antacid medicine that contains aluminum or magnesium, take it either 4 hours before or 4 hours after you take your dose of VOSEVI.
- It is important that you do not miss or skip doses of VOSEVI during treatment.
- If you take too much VOSEVI, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of VOSEVI?

VOSEVI may cause serious side effects, including:

- **Hepatitis B virus (HBV) reactivation.** See “What is the most important information I should know about VOSEVI?”
- **In people who had or have advanced liver problems before starting treatment with VOSEVI: rare risk of worsening liver problems, liver failure and death.** Your healthcare provider will check you for signs and symptoms of worsening liver problems during treatment with VOSEVI. Tell your healthcare provider right away if you have any of the following signs and symptoms:
 - nausea
 - tiredness
 - yellowing of your skin or white part of your eyes
 - bleeding or bruising more easily than normal
 - confusion
 - dark, black, or bloody stool
 - loss of appetite
 - diarrhea
 - dark or brown (tea-colored) urine
 - swelling of your stomach area (abdomen) or pain on the upper right side of your stomach area
 - sleepiness
 - vomiting of blood
 - lightheadedness
- **Slow heart rate (bradycardia).** VOSEVI treatment may result in slowing of the heart rate along with other symptoms when taken with amiodarone (Cordarone®, Nexterone®, Pacerone®), a medicine used to treat certain heart problems. In some cases, bradycardia has led to death or the need for a heart pacemaker when amiodarone is taken with medicines similar to VOSEVI that contain sofosbuvir. Get medical help right away if you take amiodarone with VOSEVI and get any of the following symptoms:
 - fainting or near-fainting
 - dizziness or lightheadedness
 - not feeling well
 - weakness
 - extreme tiredness
 - shortness of breath
 - chest pains
 - confusion
 - memory problems
- The most common side effects of VOSEVI include headache, tiredness, diarrhea, and nausea. These are not all the possible side effects of VOSEVI. 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 VOSEVI?

- Store VOSEVI below 86 °F (30 °C).
- Keep VOSEVI in its original container.

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

General information about the safe and effective use of VOSEVI

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use VOSEVI for a condition for which it was not prescribed. Do not give VOSEVI 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 VOSEVI that is written for health professionals.

What are the ingredients in VOSEVI?

Active ingredients: sofosbuvir, velpatasvir, and voxilaprevir

Inactive ingredients: colloidal silicon dioxide, copovidone, croscarmellose sodium, lactose monohydrate, magnesium stearate, and microcrystalline cellulose.

The tablet film-coat contains: ferrousferrous oxide, iron oxide red, iron oxide yellow, polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.

Manufactured and distributed by:

Gilead Sciences, Inc., Foster City, CA 94404

For more information, call 1-800-445-3235 or go to www.VOSEVI.com.

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