

Patient Information
SOVALDI® (soh-VAHL-dee)
(sofosbuvir)
tablets

Important: SOVALDI is used in combination with other antiviral medicines. When taking SOVALDI with ribavirin or in combination with peginterferon alfa and ribavirin you should also read those Medication Guides. The information in this Patient Information Leaflet talks about SOVALDI when it is used with ribavirin and in combination with peginterferon alfa and ribavirin.

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

SOVALDI can cause serious side effects, including:

- **Hepatitis B virus reactivation:** Before starting treatment with SOVALDI, 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 SOVALDI. 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 SOVALDI.

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

What is SOVALDI?

SOVALDI is a prescription medicine used with other antiviral medicines to treat adults with chronic (lasting a long time) hepatitis C virus (HCV):

- genotype 1 or 4 infection without cirrhosis or with compensated cirrhosis in combination with peginterferon alfa and ribavirin
- genotype 2 or 3 infection without cirrhosis or with compensated cirrhosis in combination with ribavirin

SOVALDI is used to treat children 12 years of age and older or weighing at least 77 pounds (at least 35 kg) with chronic HCV genotype 2 or 3 infection without cirrhosis or with compensated cirrhosis in combination with ribavirin.

It is not known if SOVALDI is safe and effective in children under 12 years of age and weighing less than 77 pounds (less than 35 kg) with HCV genotype 2 or 3 infection, or with HCV genotype 1 or 4 infection. It is not known if SOVALDI is safe and effective in people who have had a liver transplant.

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

- have ever had hepatitis B virus infection
- have liver problems other than hepatitis C infection
- have had a liver transplant
- have severe kidney problems or you are on dialysis
- have HIV infection
- are pregnant or plan to become pregnant. It is not known if SOVALDI will harm your unborn baby.
 - **Males and females who take SOVALDI in combination with ribavirin should also read the ribavirin Medication Guide for important pregnancy, contraception, and infertility information.**
- are breastfeeding or plan to breastfeed. It is not known if SOVALDI passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with SOVALDI.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. SOVALDI and other medicines may affect each other. This can cause you to have too much or not enough SOVALDI or other medicines in your body. This may affect the way SOVALDI 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 SOVALDI.
- **Do not start taking a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take SOVALDI with other medicines.

How should I take SOVALDI?

- Take SOVALDI exactly as your healthcare provider tells you to take it. Do not change your dose unless your healthcare provider tells you to.
- Do not stop taking SOVALDI without first talking with your healthcare provider.
- Take 1 SOVALDI tablet one time each day only.
- Take SOVALDI with or without food.
- If you take too much SOVALDI, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of SOVALDI?

SOVALDI can cause serious side effects, including:

- **Hepatitis B virus reactivation.** See “What is the most important information I should know about SOVALDI?”
- **Slow heart rate (bradycardia).** SOVALDI 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 SOVALDI. Get medical help right away if you take amiodarone with SOVALDI and get any of the following symptoms:
 - fainting or near-fainting
 - dizziness or lightheadedness
 - not feeling well
 - weakness
 - extreme tiredness
 - shortness of breath
 - chest pain
 - confusion
 - memory problems

The most common side effects of SOVALDI when used in combination with ribavirin include:

- tiredness
- headache

The most common side effects of SOVALDI when used in combination with peginterferon alfa and ribavirin include:

- tiredness
- headache
- nausea
- difficulty sleeping
- low red blood cell count

These are not all the possible side effects of SOVALDI. For more information, ask your healthcare provider or pharmacist.

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 SOVALDI?

- Store SOVALDI at room temperature below 86°F (30°C).
- Keep SOVALDI in its original container.
- Do not use SOVALDI if the seal over the bottle opening is broken or missing.

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

General information about the safe and effective use of SOVALDI.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use SOVALDI for a condition for which it was not prescribed. Do not give SOVALDI to other people, even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for information about SOVALDI that is written for health professionals. For more information, call 1-800-445-3235 or go to www.SOVALDI.com.

What are the ingredients in SOVALDI?

Active ingredient: sofosbuvir

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, mannitol, and microcrystalline cellulose. The tablet film-coat contains polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide, and yellow iron oxide.

Gilead Sciences, Inc., Foster City, CA 94404

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