

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

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

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 chronic (lasting a long time) hepatitis C virus genotype 1, 2, 3, or 4 infection in adults.

It is not known if SOVALDI is safe and effective in children under 18 years of age.

What should I tell my healthcare provider before taking SOVALDI?

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
- have any other medical condition
- are pregnant or plan to become pregnant. When taking SOVALDI in combination with ribavirin, you should also read the ribavirin Medication Guide for important pregnancy 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 if you take SOVALDI.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Other medicines may affect how SOVALDI works.

You should not take SOVALDI if you also take other medicines that contain sofosbuvir (Harvoni®).

Especially tell your healthcare provider if you take any of the following medicines:

- amiodarone (Cordarone®, Nexterone®, Pacerone®)
- carbamazepine (Carbatrol®, Epitol®, Equetro®, Tegretol®)
- oxcarbazepine (Trileptal®, Oxtellar XR™)
- phenytoin (Dilantin®, Phenytek®)
- phenobarbital (Luminal®)
- rifabutin (Mycobutin®)
- rifampin (Rifadin®, Rifamate®, Rifater®, Rimactane®)
- rifapentine (Priftin®)
- St. John's wort (*Hypericum perforatum*) or a product that contains St. John's wort
- tipranavir (Aptivus®)

Know the medicines you take. 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 SOVALDI?

- Take 1 tablet of SOVALDI 1 time each day only, with or without food.
- 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. If you think there is a reason to stop taking SOVALDI, talk to your healthcare provider before doing so.
- If you miss a dose of SOVALDI, take the missed dose as soon as you remember the same day. Do not take more than 1 tablet (400 mg) of SOVALDI in a day. Take your next dose of SOVALDI at your regular time the next day.
- 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 pains
 - 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

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

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

It is not known if treatment with SOVALDI will prevent you from infecting another person with the hepatitis C virus during treatment. Talk with your healthcare provider about ways to prevent spreading the hepatitis C virus.

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.

If you would like more information about SOVALDI, talk with your healthcare provider. 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.

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

Manufactured and distributed by:
Gilead Sciences, Inc.
Foster City, CA 94404

Issued: February 2017

SOVALDI and HARVONI are trademarks of Gilead Sciences, Inc., or its related companies. All other trademarks referenced herein are the property of their respective owners.

©2017 Gilead Sciences, Inc. All rights reserved.

204671-GS-004