

Patient Information

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

SOVALDI® (soh-VAHL-dee)
(sofosbuvir)
oral pellets

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 3 years of age and older 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 3 years of age 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 SOVALDI tablets or oral pellets by mouth, with or without food.
- For adults the usual dose of SOVALDI is one 400 mg tablet each day.
- For children 3 years of age and older, your healthcare provider will prescribe the right dose of SOVALDI tablets or oral pellets based on your child's body weight.
 - Tell your healthcare provider if your child has problems with swallowing tablets.
 - If your healthcare provider prescribes SOVALDI pellets for your child, see **“How should I give SOVALDI oral pellets to my child.”**
- Do not miss a dose of SOVALDI. Missing a dose lowers the amount of medicine in your blood. Refill your SOVALDI prescription before you run out of medicine.
- If you take too much SOVALDI, call your healthcare provider or go to the nearest hospital emergency room right away.

How should I give SOVALDI oral pellets to my child?

See the detailed Instructions for Use for information about how to give or take a dose of SOVALDI oral pellets.

- Administer SOVALDI oral pellets exactly as instructed by your healthcare provider.
- Do not open the packet until ready to use.
- Hold the SOVALDI pellets packet with the cut line on top.
- Shake the SOVALDI pellets packet gently to settle the pellets.
- Tear or cut the SOVALDI packet along the cut line.
- SOVALDI pellets can be taken right in the mouth without chewing, or with food.
- If SOVALDI pellets are taken with food, sprinkle the pellets on one or more spoonfuls of non-acidic soft food at or below room temperature. Examples of non-acidic foods include pudding, chocolate syrup, mashed potato, and ice cream. Take SOVALDI pellets within 30 minutes of gently mixing with food and swallow the entire contents without chewing to avoid a bitter taste.
- Do not store any leftover SOVALDI mixture (oral pellets mixed with food) for use at a later time. Throw away any unused portion.

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
 - weakness
 - chest pain
 - dizziness or lightheadedness
 - extreme tiredness
 - confusion
 - shortness of breath
 - memory problems
 - not feeling well

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 tablets or pellets below 86°F (30°C).
- Keep SOVALDI tablets in the original container.
- Do not use SOVALDI tablets if the seal over the bottle opening is broken or missing.
- Do not use SOVALDI pellets if the carton tamper-evident seal, or the pellets packet seal, is broken or damaged.

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, Tablets: 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.

Inactive ingredients, Oral Pellets: amino methacrylate copolymer, colloidal silicon dioxide, croscarmellose sodium, hydroxypropyl cellulose, hypromellose, lactose monohydrate, microcrystalline cellulose, polyethylene glycol, silicon dioxide, sodium lauryl sulfate, sodium stearyl fumarate, stearic acid, and talc.

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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INSTRUCTIONS FOR USE
SOVALDI® (soh-VAHL-dee)
(sofosbuvir)
pellets, for oral use

Read the Patient Information that comes with SOVALDI oral pellets for important information about SOVALDI.

This Instructions for Use contains information on how to take SOVALDI oral pellets. Be sure you understand and follow the instructions. If you have any questions, ask your healthcare provider or pharmacist.

Important Information You Need to Know Before Taking SOVALDI oral pellets

- **For oral use only** (take by mouth with or without food).
- **Do not** open the SOVALDI oral pellet packet(s) until ready to use.
- SOVALDI oral pellets are white to off-white pellets supplied as single-use packets in cartons. Each carton contains 28 packets.
- **Do not** use SOVALDI oral pellets if the carton tamper-evident seal, or the pellets packet seal, is broken or damaged.

Preparing a dose of SOVALDI oral pellets to be taken with food:

Before you prepare a dose of SOVALDI oral pellets to be taken with food, gather the following supplies:

- Daily SOVALDI oral pellet packet(s), as prescribed by your healthcare provider
- One or more spoonfuls of non-acidic soft food such as pudding, chocolate syrup, mashed potato, or ice cream
- Bowl
- Spoon
- Scissors (optional)

Step 1: Add one or more spoonfuls of non-acidic soft food to the bowl first.

Step 2: Hold the SOVALDI oral pellets packet with the cut line on top (see **Figure A**).

Step 3: Shake the packet gently to settle the pellets to the bottom of the packet (see **Figure B**).

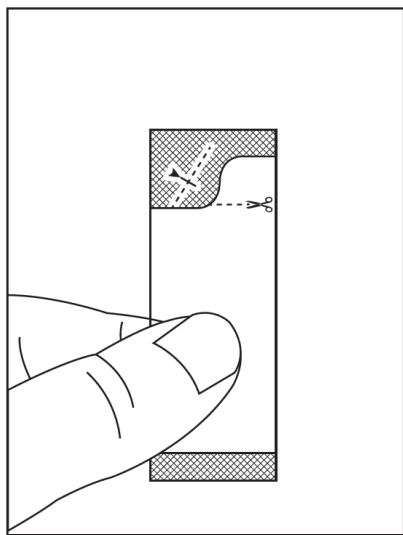


Figure A

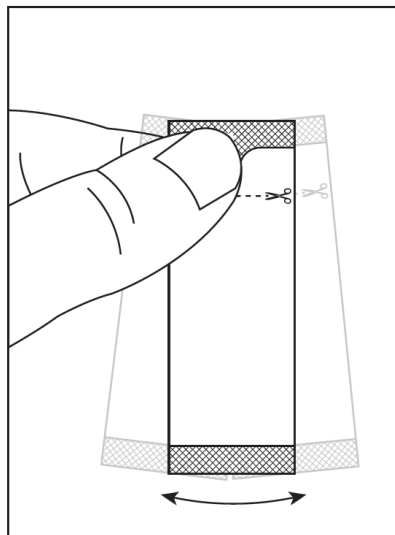


Figure B

Step 4: Cut the packet along the cut line with scissors (see **Figure C**), or fold the packet back at the tear line (see **Figure D**) and tear open (see **Figure E**).

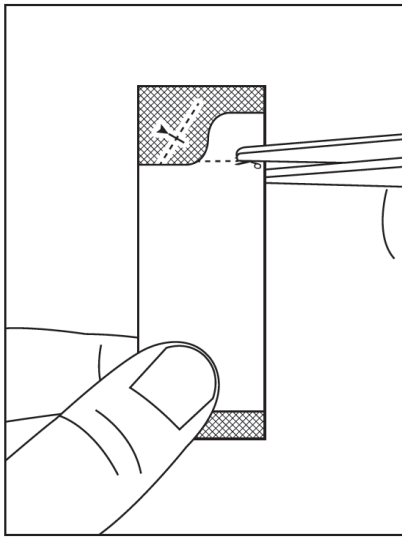


Figure C

OR

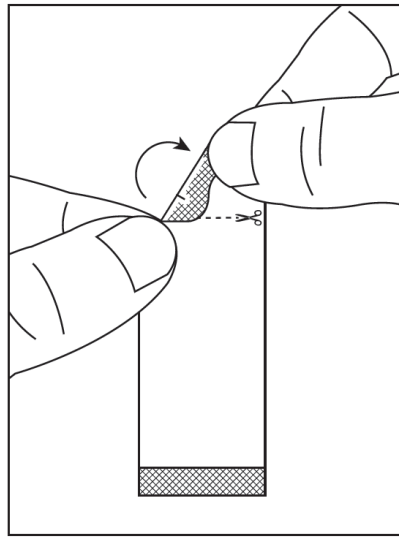


Figure D

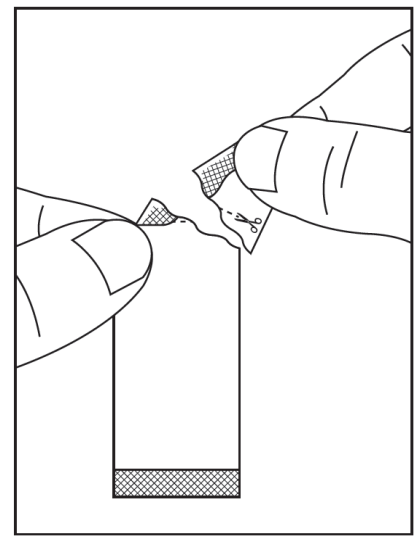


Figure E

Step 5: Carefully pour the **entire contents** of the prescribed number of SOVALDI oral pellet packet(s) onto the food in the bowl and gently mix with a spoon (see **Figure F**). Make sure that no SOVALDI oral pellets remain in the packet(s).

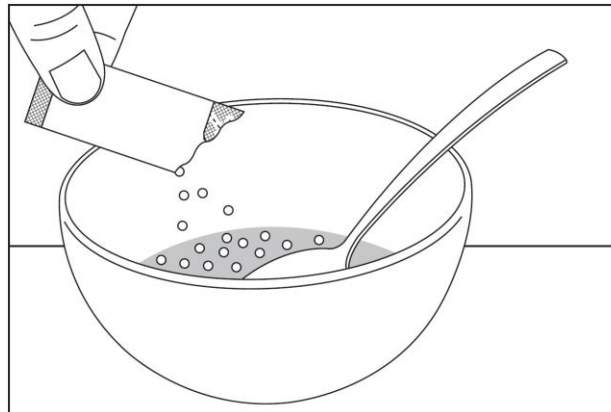


Figure F

Step 6: Take the SOVALDI oral pellets and food mixture within 30 minutes without chewing to avoid a bitter taste. **Ensure all of the SOVALDI oral pellets are taken.**

Preparing a dose of SOVALDI oral pellets to be taken without food:

Before you prepare a dose of SOVALDI oral pellets to be taken without food, gather the following supplies:

- Daily SOVALDI oral pellet packet(s), as prescribed by your healthcare provider
- Scissors (optional)
- Water (optional)

Step 1: Hold the SOVALDI oral pellets packet with the cut line on top (see **Figure G**).

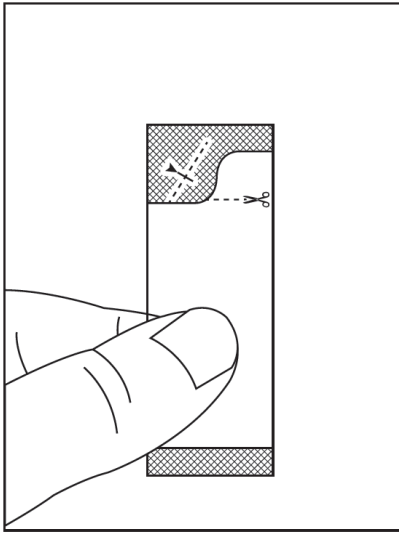


Figure G

Step 2: Shake the packet gently to settle the pellets to the bottom of the packet (see **Figure H**).

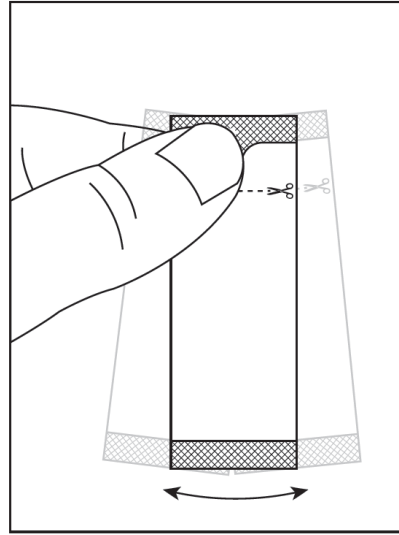


Figure H

Step 3: Cut the packet along the cut line with scissors (see **Figure I**), or fold the packet back at the tear line (see **Figure J**) and tear open (see **Figure K**).

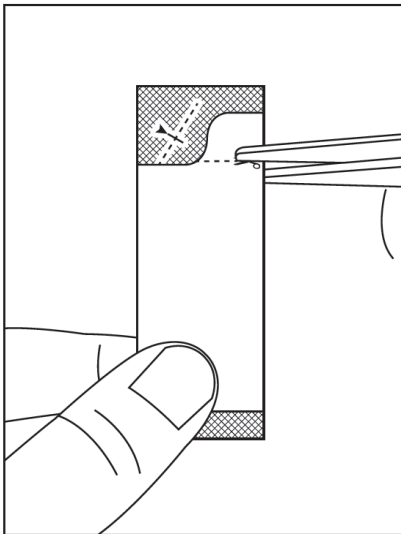


Figure I

OR

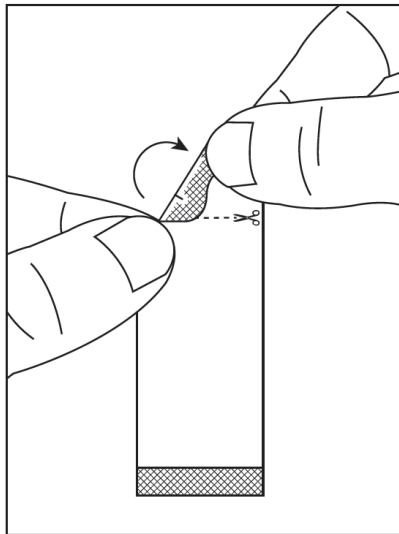


Figure J

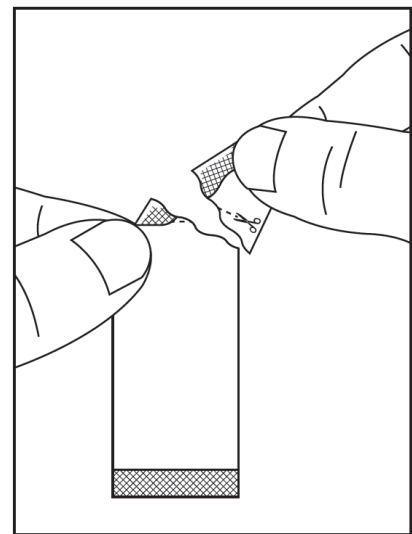


Figure K

Step 4: Pour the **entire contents** of the SOVALDI oral pellets packet directly in the mouth and swallow without chewing to avoid a bitter taste (see **Figure L**). Water may be taken after swallowing the pellets, if needed. Make sure that no SOVALDI oral pellets remain in the packet. If your healthcare provider prescribed more than one SOVALDI oral pellets packet, repeat Steps 1 through 4.

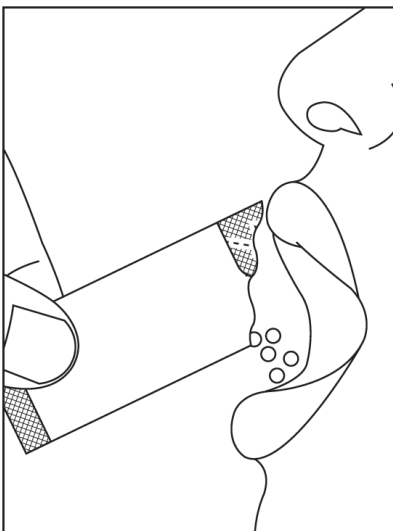


Figure L

Storing SOVALDI oral pellets

- Store SOVALDI pellets below 86°F (30°C).
 - **Keep SOVALDI oral pellets and all medicines out of the reach of children.**

Disposing of SOVALDI oral pellets

- Throw away any unused portion. Do not store and reuse any leftover SOVALDI mixture (pellets mixed with food).

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

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This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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