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2. Sovaldi

Sovaldi

Generic name: sofosbuvir [soe-FOS-bue-vir]

Drug class: Miscellaneous antivirals

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What is Sovaldi?

Sovaldi is an antiviral medication that prevents hepatitis C virus (HCV) from multiplying in your body.

Sovaldi is used to treat chronic hepatitis C in adults and children who are at least 3 years old.

Sovaldi must be given in combination with other antiviral medications (usually ribavirin with or without peginterferon alfa). It should not be used alone.

Sovaldi treats specific genotypes of hepatitis C, and only in certain people. Use only the medications prescribed for you. Do not share your medicine with other people.

Sovaldi is sometimes used in people who also have HIV, or people who have liver cancer and are going to have a liver transplant. This medicine is not a treatment for HIV or AIDS.

Warnings

If you've ever had hepatitis B, it may become active or get worse while using or after you stop using Sovaldi. You may need frequent liver function tests for several months.

Sovaldi is used in combination with other medication. Read the medication guide or patient instructions provided with each medication in your combination therapy. Do not change your doses or medication schedule without your doctor's advice.

Sovaldi can cause birth defects or death in an unborn baby. **Do not use Sovaldi with ribavirin if you are pregnant, or if you are a man and your female sexual partner is pregnant.** Use at least 2 effective forms of non-hormonal birth control while using these medicines together and for at least 6 months after treatment ends.

Before taking this medicine

You should not use Sovaldi if you are allergic to sofosbuvir. When taking Sovaldi with other medicine: To make sure all medicines are safe for you, tell your doctor about all your medical conditions, and if you are pregnant or

breastfeeding.

To make sure Sovaldi is safe for you, tell your doctor if you have ever had:

- hepatitis B (you may be tested for this before you take sofosbuvir);
- · a liver transplant;
- liver problems other than hepatitis C;
- kidney disease (or if you are on dialysis);
- . HIV or AIDS:
- a heart rhythm problem for which you take a medicine called amiodarone; or
- if you use a blood thinner (warfarin, Coumadin, Jantoven) and you have routine "INR" or prothrombin time tests.

Sovaldi is sometimes used in combination with ribavirin. **Both men and women using ribavirin should use effective birth control to prevent pregnancy.** Ribavirin can cause birth defects, miscarriage, or death to an unborn baby if the mother or father is using this medicine.

You should not take ribavirin if you are pregnant, or if you are a man and your sex partner is pregnant. Use effective birth control to prevent pregnancy. Keep using birth control for at least 6 months after your last dose of ribavirin.

Tell your doctor right away if a pregnancy occurs while either the mother or the father is using ribavirin.

It may not be safe to breastfeed while using Sovaldi. Ask your doctor about any risk.

Sovaldi is not approved for use by anyone younger than 3 years old.

Sovaldi pregnancy and breastfeeding warnings (more detail)

How should I take Sovaldi?

Sovaldi must be given in combination with other antiviral medications and it should not be used alone.

Follow all directions on your prescription label and read all medication guides or instruction sheets. Use the medicine exactly as directed.

Take the medicine at the same time each day, with or without food.

Do not chew Sovaldi oral pellets. To take with food, you may mix the pellets with a non-acidic soft food (pudding, chocolate syrup, mashed potato, ice cream) that is at room temperature or below. Swallow the mixture without chewing, no more than 30 minutes after mixing. Do not save the mixture for later use.

Sofosbuvir doses are based on weight in children. Your child's dose needs may change if the child gains or loses weight.

You will need frequent blood tests to check your liver function.

If you've ever had hepatitis B, this virus may become active or get worse while you are using Sovaldi or in the months after you stop. You may need liver function tests for several months after your last dose.

You should not stop using Sovaldi suddenly. Stopping suddenly could make your hepatitis C harder to treat with antiviral medicine.

Use all medications as directed and read all medication guides you receive. Do not change your dose or dosing schedule without your doctor's advice. Every person with chronic hepatitis C should remain under the care of a doctor.

Store this medicine in the original container at room temperature away from moisture and heat. Do not open the packet of **oral pellets** until you are ready to use the medicine.

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Sovaldi patient tips (more detail)

Dosing information

Usual Adult Dose for Chronic Hepatitis C:

400 mg orally once a day

Recommended Regimen and Duration of Therapy:

- -Genotype 1 or 4: Sofosbuvir, peginterferon alfa, and ribavirin for 12 weeks
- -Genotype 2: Sofosbuvir and ribavirin for 12 weeks
- -Genotype 3: Sofosbuvir and ribavirin for 24 weeks
- -Hepatocellular carcinoma awaiting liver transplantation: Sofosbuvir and ribavirin for up to 48 weeks or until liver transplantation (whichever occurs first)

Comments:

- -Genotype 1, 4: This regimen is recommended for therapy-naive patients without cirrhosis or with compensated cirrhosis (Child-Pugh A).
- -Genotype 2, 3: Both regimens are recommended for therapy-naive and therapy-experienced patients without cirrhosis or with compensated cirrhosis (Child-Pugh A).
- -Therapy-experienced patients have failed an interferon-based regimen (with or without ribavirin).
- -The dose recommendations for genotype 1, 2, 3, or 4 should be followed for HCV/HIV-1-coinfected patients.
- -The manufacturer product information should be consulted for ribavirin tablet dose recommendations; with genotype 1 or
- 4, the manufacturer product information for peginterferon alfa should also be consulted for dose recommendations.
- -Sofosbuvir and ribavirin for 24 weeks can be considered for patients with genotype 1 infection who cannot use an interferon-based regimen; treatment decision should be guided by benefit/risk assessment for the individual patient.
- -The regimen for patients with hepatocellular carcinoma awaiting liver transplantation is recommended to prevent posttransplant HCV reinfection.

Use: As a part of a combination antiviral treatment regimen, for the treatment of chronic HCV infection

- -In combination with pegylated interferon and ribavirin: For genotype 1 or 4 infection without cirrhosis or with compensated cirrhosis
- -In combination with ribavirin: For genotype 2 or 3 infection without cirrhosis or with compensated cirrhosis

Usual Pediatric Dose for Chronic Hepatitis C:

3 years or older:

- -Weight less than 17 kg: 150 mg orally once a day
- -Weight 17 to less than 35 kg: 200 mg orally once a day
- -Weight at least 35 kg: 400 mg orally once a day

Recommended Regimen and Duration of Therapy:

-Genotype 2: Sofosbuvir and ribavirin for 12 weeks

- -Genotype 3: Sofosbuvir and ribavirin for 24 weeks
- -Hepatocellular carcinoma awaiting liver transplantation: Sofosbuvir and ribavirin for up to 48 weeks or until liver transplantation (whichever occurs first)

Comments:

- -Both regimens are recommended for therapy-naive and therapy-experienced patients without cirrhosis or with compensated cirrhosis (Child-Pugh A).
- -Therapy-experienced patients have failed an interferon-based regimen (with or without ribavirin).
- -The manufacturer product information should be consulted for ribavirin dose recommendations.
- -The same dose recommendations should be followed for HCV/HIV-1-coinfected patients.
- -The regimen for patients with hepatocellular carcinoma awaiting liver transplantation is recommended to prevent posttransplant HCV reinfection.

Use: In combination with ribavirin, for the treatment of chronic HCV genotype 2 or 3 infection in patients without cirrhosis or with compensated cirrhosis

Detailed Sovaldi dosage information

What happens if I miss a dose?

Take the medicine as soon as you can, but skip the missed dose if it is almost time for your next dose. Do not take two doses at one time.

Get your prescription refilled before you run out of medicine completely.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

What to avoid

Avoid taking an herbal supplement containing St. John's wort.

Using this medicine will not prevent your disease from spreading. Do not have unprotected sex or share razors or toothbrushes. Talk with your doctor about safe ways to prevent hepatitis C transmission during sex. Sharing drug or medicine needles is never safe, even for a healthy person.

Sovaldi side effects

Get emergency medical help if you have **signs of an allergic reaction to Sovaldi:** hives; difficult breathing; swelling of your face, lips, tongue, or throat.

Call your doctor at once if you have new or worsening symptoms such as:

- right-sided upper stomach pain, vomiting, loss of appetite;
- · dark urine, clay-colored stools; or
- jaundice (yellowing of the skin or eyes).

If you take Sovaldi and you also take a heart rhythm medicine called amiodarone: This combination of medicines can cause dangerous side effects on your heart. Get medical help right away if you take these medicines and you have:

- · very slow heartbeats, chest pain, shortness of breath;
- · confusion, memory problems; or
- weakness, extreme tiredness, light-headed feeling (like you might pass out).

Common Sovaldi side effects may include:

- · headache, feeling tired;
- · anemia;
- · nausea, loss of appetite; or
- sleep problems (insomnia).

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Sovaldi side effects (more detail)

Related/similar drugs

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Reviews & ratings

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Glecaprevir/pibrentasvir (Mavyret) is an oral combination medicine containing fixed doses of 2 ...

Reviews & ratings

8.3 / 10

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What other drugs will affect Sovaldi?

When you start or stop taking Sovaldi, your doctor may need to adjust the doses of any other medicines you take on a regular basis.

Sometimes it is not safe to use certain medications at the same time. Some drugs can affect your blood levels of other drugs you take, which may increase side effects or make the medications less effective.

Many drugs can interact with sofosbuvir. This includes prescription and over-the-counter medicines, vitamins, and herbal products. Not all possible interactions are listed here. Tell your doctor about all your current medicines and any medicine you start or stop using.

Sovaldi drug interactions (more detail)

Does Sovaldi interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.

| Sovaldi | |
|-------------------|-----|
| + | |
| Enter a drug name | Add |

Popular FAQ

| What is the difference between hepatitis B and C? | ~ |
|--|----------|
| What are the new drugs for the treatment of hepatitis C? | ~ |
| Does Sovaldi cure hepatitis C? | ~ |
| How well does Sovaldi work? | ~ |

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- What is the cost of Sovaldi? Why is it so expensive?
- What is the difference between Sovaldi and Harvoni?

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- · Check interactions
- Compare alternatives
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- Reviews (47)
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- Patient tips
- During pregnancy
- FDA approval history
- Drug class: miscellaneous antivirals
- Breastfeeding
- En español

Professional resources

- Sovaldi prescribing information
- Sofosbuvir (AHFS Monograph)

Related treatment guides

• Hepatitis C

Further information

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use Sovaldi only for the indication prescribed.

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

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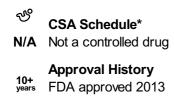
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47 Reviews

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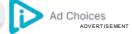
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