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Ledipasvir and sofosbuvir

Pronunciation: *led-dee-pas-vir and so-foss-bu-vir***Generic name:** ledipasvir and sofosbuvir**Brand name:** [Harvoni](#)**Dosage form:** oral tablets, oral pellets**Drug class:** [Antiviral combinations](#)Medically reviewed by [Carmen Pope, BPharm](#). Last updated on Oct 8, 2024.[Uses](#) [Cost](#) [Side effects](#) [Before taking](#) [Dosage](#) [Interactions](#) [FAQ](#)

What is ledipasvir and sofosbuvir?

Ledipasvir and sofosbuvir (brand name [Harvoni](#)) may be used to treat chronic hepatitis C virus (HCV) in adults and children aged 3 years and older. Ledipasvir sofosbuvir is used to treat the following types of HCV:

- HCV genotypes 1, 4, 5, or 6 infections without cirrhosis or with compensated cirrhosis
- HCV genotype 1 infection with advanced cirrhosis (decompensated) in combination with ribavirin
- HCV genotype 1 or 4 infection without cirrhosis or with compensated cirrhosis who have had a liver transplant, in combination with ribavirin.

Your doctor will perform tests to find out which hepatitis genotype you have. The treatment duration of ledipasvir and sofosbuvir is usually 12 weeks.

Ledipasvir sofosbuvir contains 2 antivirals, ledipasvir and sofosbuvir which each have a different mechanism of action. Ledipasvir blocks the effects of an HCV protein that is required for the virus to multiply (called viral replication). Sofosbuvir is a prodrug, that is converted in the body to its active metabolite that uses an enzyme to incorporate itself into the RNA of HCV which also prevents the virus from making copies of itself. For more information about ledipasvir and sofosbuvir's mechanism of action see [here](#).

Ledipasvir and sofosbuvir gained FDA approval for HCV on October 10, 2014, under the brand Harvoni.

Ledipasvir and sofosbuvir is available as Harvoni and as generic ledipasvir 90 mg and sofosbuvir 400 mg. There is no generic for the other strength (ledipasvir 45 mg sofosbuvir 200 mg) or for ledipasvir and sofosbuvir oral pellets. The pellets are only available as Harvoni.

Ledipasvir and sofosbuvir cost

Most insurance companies and Medicare cover the cost of ledipasvir and sofosbuvir; however, you may have to meet certain criteria and you should always check with your insurance company first before you and your doctor make it your

preferred treatment. There may also be a co-pay.

See [How Much Does Harvoni Cost?](#) for more information about the cost of Harvoni as well as Gilead's Support Path patient assistance program for Harvoni.

Ledipasvir and sofosbuvir side effects

The **most common side effects of ledipasvir and sofosbuvir** include:

- tiredness
- headache
- weakness.

Serious side effects and warnings

Ledipasvir and sofosbuvir carries a **Boxed Warning** for the risk of hepatitis B (HBV) reactivation in people coinfecting with HCV and HBV.

Hepatitis B virus (HBV) reactivation. Before starting treatment with ledipasvir and sofosbuvir, your healthcare provider will do blood tests to check for HBV. If you have ever had HBV, the hepatitis B virus could become active again during or after treatment of HCV with ledipasvir and sofosbuvir. 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 ledipasvir and sofosbuvir. Call your healthcare provider right away if you develop right-sided upper abdominal pain, vomiting, loss of appetite, or yellowing of your skin or eyes.

Slow heart rate (bradycardia). Ledipasvir and sofosbuvir may slow your heart rate and cause other symptoms when taken alongside other heart medications such as amiodarone (Cordarone, Nexterone, Pacerone). In some cases, this has led to death or the need for a heart pacemaker. Get medical help right away if you take amiodarone with ledipasvir and sofosbuvir and develop any of the following symptoms fainting or near-fainting, weakness, chest pains, dizziness or lightheadedness, extreme tiredness, confusion, not feeling well, shortness of breath, or memory problems.

Ledipasvir and sofosbuvir is used in combination with ribavirin in people with **decompensated cirrhosis**. Ribavirin can cause birth defects or death in an unborn baby. Do not use ribavirin if you are pregnant, or if you are a man and your sexual partner is pregnant. Use effective birth control to prevent pregnancy while using these medicines together and for at least 6 months after treatment ends.

It is unknown if ledipasvir and sofosbuvir is safe and effective in children under 3 years of age.

These are not all the possible side effects of ledipasvir and sofosbuvir. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

 [Ledipasvir / sofosbuvir side effects](#) (more detail)

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Before taking

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

- have ever had a hepatitis B virus infection
- have liver problems other than hepatitis C infection
- have had a liver transplant

- have kidney problems or you are on dialysis
- have HIV infection
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed.

Pregnancy

It is not known if ledipasvir and sofosbuvir will harm your unborn baby. Males and females who take ledipasvir and sofosbuvir in combination with ribavirin should also read the Ribavirin Medication Guide for important pregnancy, contraception, and infertility information.

Breastfeeding

It is not known if ledipasvir and sofosbuvir passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with ledipasvir and sofosbuvir.

i [Ledipasvir / sofosbuvir pregnancy and breastfeeding warnings](#) (more detail)

How do I take ledipasvir and sofosbuvir?

Take ledipasvir and sofosbuvir treatment 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 ledipasvir and sofosbuvir without first talking with your healthcare provider.

- Take ledipasvir and sofosbuvir tablets or oral pellets by mouth, with or without food.
- You must not miss or skip doses during treatment.
- ledipasvir and sofosbuvir is usually given for 12 weeks.

Ledipasvir and sofosbuvir dosage

The usual dosage of ledipasvir and sofosbuvir to treat HCV in adults is ledipasvir and sofosbuvir 90 mg/400 mg, 1 tablet each day.

The usual dosage of ledipasvir and sofosbuvir to treat HCV in children 3 years of age and older is based on body weight.

- Tell your healthcare provider if your child has problems with swallowing tablets.
- If your healthcare provider prescribes ledipasvir and sofosbuvir oral pellets (Harvoni) for your child, see below.

How should I give ledipasvir and sofosbuvir oral pellets to my child?

See the Instructions for Use in the [Harvoni Package Insert](#) for detailed information about giving or taking ledipasvir and sofosbuvir oral pellets if you or your child are prescribed ledipasvir and sofosbuvir treatment. Administer the pellets exactly as instructed by your healthcare provider.

- Do not open the packet until ready to use.
- Hold the ledipasvir and sofosbuvir pellets packet with the cut line on top.

- Shake the pellets packet gently to settle the pellets.
- Tear or cut the packet along the cut line.
- ledipasvir and sofosbuvir oral pellets can be taken with or without food.
- If your healthcare provider has prescribed more than one packet of pellets, take the next packet in the same way.

Taking ledipasvir and sofosbuvir pellets with food

If ledipasvir and sofosbuvir 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 ledipasvir and sofosbuvir pellets within 30 minutes of gently mixing them with food and swallow the entire contents without chewing to avoid a bitter taste.
- Do not store any leftover ledipasvir and sofosbuvir mixture (oral pellets mixed with food) for use at a later time. Throw away any unused portion.

Taking ledipasvir and sofosbuvir pellets without food

If ledipasvir and sofosbuvir pellets are taken **without food**, sprinkle the entire contents of the packet directly into the mouth and swallow without chewing to avoid a bitter taste.

- Water may be taken after swallowing the pellets to avoid a bitter taste. Make sure no pellets remain in the packet.

 [Detailed Ledipasvir / sofosbuvir dosage information](#)

What to avoid

Ask your doctor before using an antacid or stomach acid-reducing medicine with ledipasvir and sofosbuvir. Use only the type and amount your doctor recommends.

Using ledipasvir and sofosbuvir will not prevent your disease from spreading. Do not have unprotected sex or share razors or toothbrushes if you have HCV. Talk with your doctor about safe ways to prevent HCV transmission during sex. Sharing drugs or medicine needles is never safe, even for a healthy person.

What happens if I miss a dose?

Do not miss a dose of ledipasvir and sofosbuvir. Missing a dose lowers the amount of medicine in your blood. Refill your ledipasvir and sofosbuvir prescription before you run out of medicine.

If you miss a dose of ledipasvir and sofosbuvir, 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.

What happens if I overdose?

If you take too much ledipasvir and sofosbuvir, call your healthcare provider, call the Poison Help line at 1-800-222-1222, or go to the nearest hospital emergency room right away.

What other drugs will affect ledipasvir and sofosbuvir?

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take:

- Amiodarone, because coadministration may result in a seriously slow heartbeat (bradycardia). Amiodarone should not be used with ledipasvir and sofosbuvir
- P-gp inducers and/or moderate to strong CYP inducers (such as rifampin, St. John's wort, and carbamazepine). May decrease concentrations of ledipasvir and sofosbuvir. Use together is not recommended
- Omeprazole (Prilosec) or an antacid. Do not take them for at least 4 hours after you have taken your dose of ledipasvir and sofosbuvir because these may affect the absorption of ledipasvir and sofosbuvir.

Clearance of HCV with direct-acting antivirals may lead to changes in liver function, which may impact the safe and effective use of other medications. Frequent laboratory monitoring (INR and blood glucose) and dose adjustments may be necessary.

This is not a full list of interactions. Ask your healthcare provider or pharmacist for a list of medicines that interact with ledipasvir and sofosbuvir. Do not start taking a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take ledipasvir and sofosbuvir with other medicines.

 [Ledipasvir / sofosbuvir drug interactions](#) (more detail)

Does ledipasvir/sofosbuvir interact with my other drugs?

Enter medications to view a detailed interaction report using our [Drug Interaction Checker](#).

ledipasvir/sofosbuvir

+

Enter a drug name

Add

Storage

Store ledipasvir and sofosbuvir tablets or pellets below 86°F (30°C). Keep them in their original container. Do not use:

- Ledipasvir and sofosbuvir tablets if the seal over the bottle opening is broken or missing
- Ledipasvir and sofosbuvir pellets (brand Harvoni) if the carton tamper-evident seal, or the pellets packet seal, is broken or damaged.

Keep out of the reach of children.

Ledipasvir and sofosbuvir ingredients

Active ingredients: ledipasvir and sofosbuvir

Inactive ingredients, ledipasvir and sofosbuvir 90/400 mg (Harvoni): colloidal silicon dioxide, copovidone, croscarmellose sodium, lactose monohydrate, magnesium stearate, and microcrystalline cellulose. Tablet film-coating

contains FD&C yellow #6/sunset yellow FCF aluminum lake, polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.

Inactive ingredients, ledipasvir and sofosbuvir 45/200 mg (Harvoni): colloidal silicon dioxide, copovidone, croscarmellose sodium, lactose monohydrate, magnesium stearate, and microcrystalline cellulose. Tablet film-coat contains polyethylene glycol, polyvinyl alcohol partially hydrolyzed, talc, and titanium dioxide.

Inactive ingredients, ledipasvir and sofosbuvir Oral Pellets (Harvoni): amino-methacrylate copolymer, colloidal silicon dioxide, copovidone, croscarmellose sodium, hypromellose, iron oxide red, iron oxide yellow, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, talc, and titanium dioxide.

Who makes ledipasvir and sofosbuvir?

Gilead Sciences, Inc., makes ledipasvir and sofosbuvir under the brand name Harvoni.

- Ledipasvir and sofosbuvir tablets 90 mg/ 400 mg and 45 mg/ 200 mg
- Ledipasvir and sofosbuvir pellets 45 mg/ 200 mg, 33.75 mg/150 mg.

Asegua Therapeutics LLC., a subsidiary of Gilead Sciences Inc., makes generic ledipasvir and sofosbuvir tablets under the generic name ledipasvir 90 mg/ sofosbuvir 400 mg.

Popular FAQ

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- [Epclusa vs Harvoni – Which is better?](#)
- [What is the difference between Sovaldi and Harvoni?](#)
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References

1. [Ledipasvir and Sofosbuvir Package Insert](#)
2. [Ledipasvir and Sofosbuvir Prescribing Information](#)

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- [Ledipasvir and Sofosbuvir Tablets \(FDA\)](#)

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Further information

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

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DRUG STATUS

Availability

Rx Prescription only

[Pregnancy & Lactation](#)

 Risk data available

CSA Schedule*

N/A Not a controlled drug



Approval History



Drug history at FDA



User Reviews & Ratings

8.3 / 10

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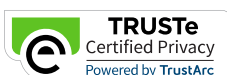
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