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Harvoni

Pronunciation: *har-VOE-nee*

Generic name: [ledipasvir and sofosbuvir](#)

Dosage form: oral tablets, oral pellets

Drug class: [Antiviral combinations](#)

Medically reviewed by [Carmen Pope, BPharm](#). Last updated on Nov 20, 2024.

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What is Harvoni?

Harvoni is used to treat hepatitis C virus (HCV) infections in adults and children aged 3 years and older.

Harvoni's mechanism of action involves preventing HCV from replicating (making copies of itself) in the body. Harvoni contains 2 antivirals, ledipasvir and sofosbuvir. Each has a different mechanism of action. Ledipasvir blocks the effects of an HCV protein required for HCV replication. Sofosbuvir is converted in the body to its active metabolite which incorporates itself into the RNA of HCV, also preventing HCV replication. from making copies of itself. See [What is the mechanism of action of Harvoni?](#) for more information.

Harvoni gained FDA approval for HCV on October 10, 2014. A [Harvoni generic](#) is available as ledipasvir 90 mg and sofosbuvir 400 mg. There is no Harvoni generic for the other strength of Harvoni (ledipasvir 45 mg sofosbuvir 200 mg) or Harvoni oral pellets.

Harvoni uses

Harvoni is used for HCV genotypes 1, 4, 5, or 6 infections without cirrhosis or with compensated cirrhosis.

Harvoni also treats HCV genotype 1 infection with advanced cirrhosis (decompensated) in combination with ribavirin and people with 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 Harvoni is usually 12 weeks.

Harvoni cost

Most insurance companies and Medicare cover the cost of Harvoni; 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.

Harvoni side effects

The **most common side effects of Harvoni** include:

- tiredness
- headache
- weakness.

Serious side effects and warnings

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

Hepatitis B virus (HBV) reactivation. Before starting treatment with Harvoni, 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 Harvoni. 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 Harvoni. 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). Harvoni 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 Harvoni 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.

Harvoni 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 Harvoni is safe and effective in children under 3 years of age.

These are not all the possible side effects of Harvoni. 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.

 [Harvoni side effects](#) (more detail)

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Before taking

Before taking Harvoni, 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 Harvoni will harm your unborn baby. Males and females who take Harvoni in combination with ribavirin should also read the Ribavirin Medication Guide for important pregnancy, contraception, and infertility information.

Breastfeeding

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

 [Harvoni pregnancy and breastfeeding warnings](#) (more detail)

How do I take Harvoni?

Take Harvoni 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 Harvoni without first talking with your healthcare provider.

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

 [Detailed Harvoni dosage information](#)

Harvoni treatment

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

The usual dosage of Harvoni 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 Harvoni oral pellets for your child, see below.

How should I give Harvoni oral pellets to my child?

See the Instructions for Use in the Harvoni Package insert for detailed information about giving or taking Harvoni oral pellets if you or your child are prescribed Harvoni treatment. Administer the pellets exactly as instructed by your healthcare provider.

- Do not open the packet until ready to use.
- Hold the Harvoni 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.
- Harvoni 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 Harvoni pellets with food

If Harvoni 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 Harvoni 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 Harvoni mixture (oral pellets mixed with food) for use at a later time. Throw away any unused portion.

Taking Harvoni pellets without food

If Harvoni 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.

What to avoid

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

Using Harvoni 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 Harvoni. Missing a dose lowers the amount of medicine in your blood. Refill your Harvoni prescription before you run out of medicine.

If you miss a dose of Harvoni, 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 Harvoni, 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 Harvoni?

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 Harvoni
- P-gp inducers and/or moderate to strong CYP inducers (such as rifampin, St. John's wort, and carbamazepine). May decrease concentrations of Harvoni. 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 Harvoni because these may affect the absorption of Harvoni.

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 Harvoni. Do not start taking a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take Harvoni with other medicines.

 [Harvoni drug interactions](#) (more detail)

Does Harvoni interact with my other drugs?

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

Harvoni

+

Enter a drug name

Add

Storage

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

- Harvoni tablets if the seal over the bottle opening is broken or missing
- Harvoni pellets if the carton tamper-evident seal, or the pellets packet seal, is broken or damaged.

Keep out of the reach of children.

Harvoni ingredients

Active ingredients: ledipasvir and sofosbuvir

Inactive ingredients, Harvoni 90/400 mg: 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, Harvoni 45/200 mg: 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, Harvoni Oral Pellets: 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 Harvoni?

Gilead Sciences, Inc., makes Harvoni.

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

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

Popular FAQ

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References

1. [Harvoni Medication guide](#)
2. [Harvoni Package Insert](#)

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- [Hepatitis C](#)

Further information

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

[Medical Disclaimer](#)

DRUG STATUS

Availability

Rx Prescription only

Pregnancy & Lactation

 Risk data available

CSA Schedule*

N/A Not a controlled drug

Approval History

10 years FDA approved 2014



User Reviews & Ratings

8.4 / 10

[403 Reviews](#)

Images

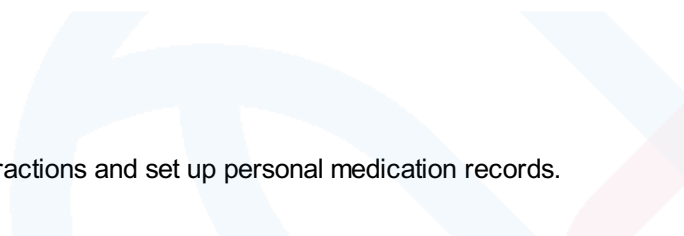
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