

Patient Information
HARVONI® (har-VOE-nee)
(ledipasvir and sofosbuvir)
tablets

Important: If you take HARVONI with ribavirin, you should also read the Medication Guide for ribavirin.

What is the most important information I should know about HARVONI?

HARVONI can cause serious side effects, including,

Hepatitis B virus reactivation: Before starting treatment with HARVONI, 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 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.

For more information about side effects, see the section “What are the possible side effects of HARVONI?”

What is HARVONI?

HARVONI is a prescription medicine used to treat adults with chronic (lasting a long time) hepatitis C virus (HCV):

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

HARVONI is used to treat children 12 years of age and older or weighing at least 77 pounds (at least 35 kg) with chronic HCV genotype 1, 4, 5, or 6 without cirrhosis or with compensated cirrhosis.

It is not known if HARVONI is safe and effective in children with HCV under 12 years of age and weighing less than 77 pounds (less than 35 kg), with advanced cirrhosis (decompensated), or who have had a liver transplant.

Before taking HARVONI, 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 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.**
- are breastfeeding or plan to breastfeed. 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.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. HARVONI and other medicines may affect each other. This can cause you to have too much or not enough HARVONI or other medicines in your body. This may affect the way HARVONI 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 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.

How should I take HARVONI?

- Take HARVONI 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 1 HARVONI tablet one time each day and at the same time each day.
- Take HARVONI with or without food.
- It is important that you do not miss or skip doses of HARVONI during treatment.

If you take too much HARVONI, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of HARVONI?**HARVONI can cause serious side effects, including:**

- **Hepatitis B virus reactivation.** See “What is the most important information I should know about HARVONI?”
- **Slow heart rate (bradycardia).** HARVONI 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 HARVONI. Get medical help right away if you take amiodarone with HARVONI 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 HARVONI include:

- tiredness
- headache
- weakness

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 FDA at 1-800-FDA-1088.

How should I store HARVONI?

- Store HARVONI at room temperature below 86°F (30°C).
- Keep HARVONI in its original container.
- Do not use HARVONI if the seal over the bottle opening is broken or missing.

Keep HARVONI and all medicines out of the reach of children.

General information about the safe and effective use of HARVONI

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use HARVONI for a condition for which it was not prescribed. Do not give HARVONI 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 HARVONI that is written for health professionals.

What are the ingredients in HARVONI?

Active ingredients: ledipasvir and sofosbuvir

Inactive ingredients: colloidal silicon dioxide, copovidone, croscarmellose sodium, lactose monohydrate, magnesium stearate, and microcrystalline cellulose.

The tablet film-coat contains: FD&C yellow #6/sunset yellow FCF aluminum lake, polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.

Manufactured and distributed by:

Gilead Sciences, Inc., Foster City, CA 94404

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

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

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