



(har-VOE-nee)

IMPORTANT FACTS

This is only a brief summary of important information about HARVONI and does not replace talking to your healthcare provider about your condition and your treatment.

MOST IMPORTANT INFORMATION 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 infection. If you have ever had hepatitis B, the hepatitis B virus could become active again during or after treatment with HARVONI. This may cause serious liver problems, including liver failure and death. Your healthcare provider will monitor you if you are at risk for hepatitis B reactivation during and after you stop taking HARVONI.

ABOUT HARVONI

HARVONI is a prescription medicine used to treat adults and children 3 years of age and older with chronic (lasting a long time) hepatitis C genotype (GT) 1, 4, 5, or 6 infection with or without cirrhosis (compensated). In people with GT 1 infection and advanced cirrhosis (decompensated) or with GT 1 or 4 infection with or without cirrhosis (compensated) who have had a liver transplant, HARVONI is used with ribavirin.

POSSIBLE SIDE EFFECTS OF HARVONI

HARVONI can cause serious side effects, including:

- Those in the “Most Important Information about HARVONI” section.
- **Slow heart rate (bradycardia):** HARVONI, when taken with amiodarone (Cordarone®, Nexterone®, Pacerone®), a medicine used to treat certain heart problems, may cause slow heart rate, which in some cases has led to death or the need for a pacemaker. 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, and 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.

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
- had a liver transplant
- have kidney problems or are on dialysis
- have HIV infection
- are pregnant or breastfeeding, or plan to become pregnant or breastfeed
 - If you take HARVONI with ribavirin, you should also read the ribavirin Medication Guide for important pregnancy-related information.

Tell your healthcare provider about all the medicines you take:

- Keep a list that includes all prescription and over-the-counter medicines, vitamins, and herbal supplements, and show it to your healthcare provider.
- HARVONI and certain medicines may affect each other, or cause side effects.

GET MORE INFORMATION

- This is only a brief summary of important information about HARVONI. Talk to your healthcare provider or pharmacist to learn more.
- Go to HARVONI.com or call 1-844-READY41.
- To learn about potential savings, call 1-855-7-MYPATH or go to HARVONI.com/support.

