

Patient Information

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

Read this Patient Information before you start taking HARVONI and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is HARVONI?

- HARVONI is a prescription medicine used to treat chronic (lasting a long time) hepatitis C genotype 1 infection in adults.
- HARVONI contains the prescription medicines ledipasvir and sofosbuvir (SOVALDI®).

It is not known if HARVONI is safe and effective in children under 18 years of age.

What should I tell my healthcare provider before taking HARVONI?

Before taking HARVONI, tell your healthcare provider if you:

- have liver problems other than hepatitis C infection
- have severe kidney problems or you are on dialysis
- have any other medical condition
- are pregnant or plan to become pregnant. It is not known if HARVONI will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if HARVONI passes into your breast milk.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. HARVONI may affect the way other medicines work, and other medicines may affect how HARVONI works.

You should not take HARVONI if you also take other medicines that contain sofosbuvir (SOVALDI®).

Especially tell your healthcare provider if you take any of the following medicines:

- an antacid that contains aluminum or magnesium hydroxide. If you take an antacid during treatment with HARVONI, take the antacid 4 hours before or 4 hours after you take HARVONI.

- amiodarone (Cordarone[®], Nexterone[®] Pacerone[®])
- carbamazepine (Carbatrol[®], Epitol[®], Equetro[®], Tegretol[®])
- digoxin (Lanoxin[®])
- efavirenz, emtricitabine, tenofovir disoproxil fumarate (ATRIPLA[®])
- elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil fumarate (STRIBILD[®])
- medicines for indigestion, heartburn, or stomach ulcers, such as nizatidine (Axid[®]), famotidine (Pepcid AC[®]), cimetidine (Tagamet[®]), ranitidine (Zantac[®]), esomeprazole (Nexium[®]), lansoprazole (Prevacid[®]), omeprazole (Prilosec[®]), rabeprazole (Aciphex[®]), or pantoprazole (Protonix[®])
- oxcarbazepine (Trileptal[®], Oxtellar XR[®])
- phenytoin (Dilantin[®], Phenytek[®])
- phenobarbital (Luminal[®])
- rifabutin (Mycobutin[®])
- rifampin (Rifadin[®], Rifamate[®], Rifater[®], Rimactane[®])
- rifapentine (Priftin[®])
- rosuvastatin (Crestor[®])
- simeprevir (Olysio[®])
- St. John's wort (*Hypericum perforatum*) or a product that contains St. John's wort
- tipranavir (Aptivus[®]) used in combination with ritonavir (Norvir[®])
- tenofovir disoproxil fumarate (VIREAD[®], TRUVADA[®]) used in combination with atazanavir (Reyataz[®]) and ritonavir (Norvir[®]), darunavir (Prezista[®]) and ritonavir (Norvir[®]), or used in combination with lopinavir and ritonavir (Kaletra[®])

Know the medicines you take. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

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. If you think there is a reason to stop taking HARVONI, talk to your healthcare provider before doing so.
- Take HARVONI 1 time each day with or without food.
- If you miss a dose of HARVONI, take the missed dose as soon as you remember the same day. Do not take more than 1 tablet of HARVONI in a day. Take your next dose of HARVONI at your regular time the next day.

- 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?

The most common side effects of HARVONI include:

- tiredness
- headache

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

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

It is not known if treatment with HARVONI will prevent you from infecting another person with the hepatitis C virus during treatment. Talk with your healthcare provider about ways to prevent spreading the hepatitis C virus.

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.

If you would like more information about HARVONI, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about HARVONI that is written for health professionals.

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

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.

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

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