

Harvoni® Tablets

ledipasvir /sofosbuvir 90 mg/400 mg tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about HARVONI tablets. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from your pharmacist or doctor and may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking HARVONI against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

What HARVONI is used for

HARVONI is used to treat hepatitis C virus infection in adults of 18 years and older.

Hepatitis C is a virus that infects the liver.

How HARVONI works

HARVONI is one tablet that contains two active substances, ledipasvir and sofosbuvir. This medicine works by lowering the amount of hepatitis C virus in your body and may lead to a cure of your HCV infection over a number of weeks.

HARVONI is sometimes taken with another medicine, ribavirin.

Cure means the HCV virus is cleared from your blood (remains at an undetectable level) when measured 3 months after finishing all treatment.

HARVONI does not protect against re-infection with the HCV virus if cure has been achieved.

Ask your doctor if you have any questions about why HARVONI has been prescribed for you.

Use in children

HARVONI is for adults. HARVONI has not been studied in children under the age of 18.

Before you take HARVONI

When you must not take it

Together with your doctor, you need to decide whether HARVONI is right for you.

Do not take HARVONI if you are allergic to:

- ledipasvir,
- sofosbuvir or
- any of the other ingredients of HARVONI. The ingredients of HARVONI are in the product description section of this leaflet.

Some people are allergic to medicines. If you have any of the following symptoms soon after taking your medicine, DO NOT TAKE

ANY MORE HARVONI and tell your doctor IMMEDIATELY or go to the accident and emergency department at your nearest hospital:

- Skin troubles such as lumpy skin rash or “hives”
- Swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- Wheezing, chest pain or tightness
- Fainting

These are very serious effects. If you have them, you may have a serious allergic reaction. You may need urgent medical attention or hospitalisation. Hypersensitivity reactions are very rare.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not take HARVONI if you are taking any medicine other than HARVONI that contains sofosbuvir.

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. You should not breast feed during treatment with HARVONI.

Do not take HARVONI after the expiry or “use by” date (EXP) printed on the bottle. If you take it after the expiry date has passed, it may not work as well.

Do not take HARVONI if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if you are allergic to foods, dyes, preservatives or any other medicines.

Tell your doctor if you have, or have had, any of the following medical conditions:

- Have liver problems, other than hepatitis C
- Have a current or previous infection with the hepatitis B virus, since your doctor may want to monitor you more closely.
- Have severe kidney problems or if you are on haemodialysis as the effects of HARVONI on patients with severe kidney problems have not been fully tested
- Have any other medical condition

Tell your doctor if you:

- Are pregnant or planning to become pregnant. Please speak to your doctor if you are unsure. HARVONI may be used with ribavirin. Ribavirin can damage your unborn baby. It is therefore absolutely essential that you (and your partner) take all precautions not to get pregnant if you are taking ribavirin. You and your partner must use an effective birth control method during ribavirin treatment and during the 6 months after completing ribavirin treatment. It is very important that you read the “Pregnancy” section in the ribavirin product information very carefully
- Are breastfeeding or plan to breast-feed. It is not known whether ledipasvir or sofosbuvir, the two active substances of HARVONI, pass into human breast milk

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking HARVONI.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and HARVONI may interfere with each other.

Tell your doctor if you take any of the following medicines:

- amiodarone used to treat heart conditions
- digoxin used to treat heart conditions
- rosuvastatin used to treat high cholesterol
- tipranavir used to treat HIV infection
- tenofovir disoproxil fumarate used to treat HIV infection
- rifampicin, rifapentine, rifabutin (antibiotics used to treat infections, including tuberculosis);
- St. John's Wort (*Hypericum perforatum* – herbal medicine used to treat depression);
- carbamazepine, phenytoin (medicines used to treat epilepsy and prevent seizures).
- Warfarin or other similar medicines called vitamin K antagonists used to thin the blood.

HARVONI may interact with these medicines. As a result, the amounts of HARVONI or other medicines in your blood may be affected. This may stop your medicines from working properly, or make any side effects worse. In some cases your doctor may need to give you a different medicine or adjust the dose of medicine you are taking.

- Take any medicines used to treat stomach ulcers, heartburn or acid reflux, such as:
 - antacids (e.g. aluminium hydroxide or magnesium hydroxide)
 - Proton pump inhibitors (e.g. omeprazole)
 - H₂-antagonists (e.g. famotidine)

These medicines can decrease the amount of ledipasvir in your blood. If you are taking one of these medicines your doctor will either give you a different medicine for stomach ulcers, heartburn or acid reflux, or recommend how and when you take that medicine.

- If you are taking an antacid, take it at least 4 hours before or at least 4 hours after HARVONI.
- If you are taking a proton pump inhibitor, take it at the same time as HARVONI or up to 2 hours after taking HARVONI. Do not take before HARVONI.
- If you are taking an H₂-antagonist, your doctor may give you a different medicine or adjust the dose of the medicine you are taking.

It is very important to let your doctor or pharmacist know what medications, herbal supplements, or vitamins you are taking.

Know the medicines you take. Keep a list of medicines and show it to your doctor and pharmacist when you get a new medicine. Your doctor and your pharmacist can tell you if you can take these medicines with HARVONI. Do not start any new medicines while you are taking HARVONI without first talking with your doctor or pharmacist.

Your doctor and pharmacist may have more information on medicines to be careful with or to avoid while taking HARVONI.

How to take HARVONI

Follow all directions given to you by your doctor or pharmacist carefully.

How much to take

The usual dose is one HARVONI tablet orally, once daily. Never change the dose on your own. Do not stop this medicine unless your doctor tells you to stop.

How to take it

HARVONI tablets can be taken with or without food.

When to take it

Take HARVONI at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

If you forget to take it

Do not miss a dose of HARVONI. If you forget to take HARVONI, take your missed dose right away unless it is almost time for your next dose.

Do not take a double dose to make up for a forgotten dose. Continue with your regular dosing schedule.

Do not stop taking HARVONI unless your doctor tells you to. It is very important that you complete the full course of treatment to give the medicines the best chance to cure your hepatitis C virus infection.

Do not change your dose or stop taking HARVONI without first talking to your doctor.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre: 131126 (Australia) and 0800 764 766 (New Zealand) or go to the Accident and Emergency department at your nearest hospital if you think you or anyone else may have taken too many HARVONI tablets. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking HARVONI

Things you must do

Tell all doctors and pharmacists who are treating you that you are taking HARVONI.

Tell your doctor as soon as possible if there is any worsening of your condition.

Things you must not do

Do not give HARVONI to anyone else, even if they have the same condition as you.

Do not stop taking HARVONI or change the dose without checking with your doctor.

It is important not to suddenly stop taking your HARVONI tablets, unless advised to do so by your doctor.

Do not breastfeed. See “Before you take it”.

Things to be careful of

Be careful driving or operating machinery until you know how HARVONI affects you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking HARVONI.

HARVONI helps most people with Hepatitis C virus infection, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. Do not be alarmed by these lists of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- tiredness
- headache
- nausea
- trouble sleeping (insomnia)
- cough, shortness of breath
- rash, itchy skin
- feeling irritable

Tell your doctor as soon as possible if you have any problems while taking HARVONI, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Tell your doctor immediately if you or your family notice any of the following side effects:

- signs of allergy such as rash or hives on the skin; swelling of the face, lips, tongue or other parts of the body; wheezing or difficulty breathing

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After taking HARVONI

Storage

Keep your HARVONI where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep HARVONI tablets in a cool, dry place where it stays below 30°C.

Do not store HARVONI or any other medicine in a bathroom or near a sink. Do not leave HARVONI in the car or on a

window sill – heat and dampness can destroy some medicines.

Keep your HARVONI tablets in the bottle with the cap tightly closed until you take them. If you take HARVONI tablets out of their pack they may not keep well.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

HARVONI tablets are diamond-shaped and orange in colour. Each tablet has “GSI” on one side and “7985” on the other side of the tablet.

HARVONI tablets are supplied in bottles containing 28 tablets.

Ingredients

Active Ingredients: ledipasvir and sofosbuvir
Inactive Ingredients: silicon dioxide, copovidone, croscarmellose sodium, lactose, magnesium stearate and microcrystalline cellulose.

Film-coating: polyvinyl alcohol, macrogol 3350, titanium dioxide, purified talc, and sunset yellow FCF aluminium lake.

Sponsor

Australia

Gilead Sciences Pty Ltd
Level 6, 417 St Kilda Road
Melbourne, Victoria 3004

New Zealand

c/- Grant Thornton New Zealand Limited,
L4, 152 Fanshawe Street
Auckland 1010

This leaflet was prepared in April 2018.

HARVONI, 7985 and GSI are trademarks of Gilead Sciences, Inc. or one of its related companies. Other brands listed are trademarks of their respective owners and are not trademarks of Gilead Sciences, Inc.

AUST R 222848