

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details. [Include if applicable]

1. Why am I using Harvoni?

Harvoni contains the active ingredients sofosbuvir and ledipasvir. Harvoni is used to treat hepatitis C virus (HCV) infection in adults 18 years and older.

For more information, see Section [1. Why am I using Harvoni?](#) in the full CMI.

2. What should I know before I use Harvoni?

Do not use if you have ever had an allergic reaction to Harvoni or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Harvoni?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Harvoni and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Harvoni?

The usual dose is one Harvoni tablet orally, once daily. Harvoni tablets can be taken with or without food.

More instructions can be found in Section [4. How do I use Harvoni?](#) in the full CMI.

5. What should I know while using Harvoni?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Harvoni.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly.• Do not give Harvoni to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how Harvoni affects you.
Looking after your medicine	<ul style="list-style-type: none">• Keep your Harvoni tablets in the bottle with the cap tightly closed until you take them.• Store Harvoni in a cool, dry place where it stays below 30 °C.

For more information, see Section [5. What should I know while using Harvoni?](#) in the full CMI.

6. Are there any side effects?

Common side effects include tiredness, headache, nausea, trouble sleeping (insomnia), cough, shortness of breath, rash, itchy skin, feeling irritable

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

HARVONI®

Active ingredient(s): *ledipasvir/sofosbuvir*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Harvoni. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Harvoni.**

Where to find information in this leaflet:

- [1. Why am I using Harvoni?](#)
- [2. What should I know before I use Harvoni?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Harvoni?](#)
- [5. What should I know while using Harvoni?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Harvoni?

Harvoni contains the active ingredient ledipasvir and sofosbuvir. Harvoni is a direct acting antiviral. 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.

Harvoni is used to treat hepatitis C virus (HCV) infection in adults and paediatric patients 12 years of age and older.

Hepatitis C is a virus that infects the liver.

2. What should I know before I use Harvoni?

Warnings

Do not use Harvoni if:

- you are allergic to ledipasvir, sofosbuvir or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- 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 kidney problems or if you are on haemodialysis.
- Have diabetes
- Have any other medical condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. 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.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known whether ledipasvir or sofosbuvir, the two active ingredients of Harvoni, pass into human breast milk.

Use in Children

Harvoni is recommended for adults. Harvoni has not been studied in children under 12 years of age.

3. What if I am taking other medicines?

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

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.

Get advice from a doctor or pharmacist if you take medicines used to treat stomach ulcers, heartburn or acid reflux. These medicines include:

- 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Harvoni.

4. How do I use Harvoni?

How much to take

- The usual dose is one Harvoni tablet orally, once daily.
- Harvoni tablets can be taken with or without food.
- Follow the instructions provided and use Harvoni until your doctor tells you to stop.

When to take Harvoni

- Harvoni should be taken at the same time each day to have the best effect. It will also help you remember when to take it.

If you forget to use Harvoni

Harvoni should be used regularly at the same time each day. If you miss your dose at the usual time, take your missed dose right away unless it is almost time for your next dose.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed. 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 medicine the best chance to cure your hepatitis C virus infection.

If you use too much Harvoni

If you think that you have used too much Harvoni, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre **by calling 13 11 26 (Australia)** or **0800 764 766 (New Zealand)**, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Harvoni?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using Harvoni.

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

Things you should not do

- Do not give Harvoni to anyone else, even if they have the same condition as you.
- Do not stop using this medicine without checking with your doctor
- Do not breastfeed.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Harvoni affects you.

Looking after your medicine

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

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight.

Do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> tiredness headache nausea trouble sleeping (insomnia) cough, shortness of breath rash, itchy skin feeling irritable 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Signs of allergic reaction such as:</p> <ul style="list-style-type: none"> 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 <p>A wide-spread severe rash with peeling skin which may be accompanied by fever, flu like symptoms, blisters in the mouth, eyes, and/or genitals (Stevens-Johnson syndrome)</p>	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Harvoni contains

Active ingredient (main ingredient)	ledipasvir sofosbuvir
Other ingredients (inactive ingredients)	silicon dioxide copovidone croscarmellose sodium lactose magnesium stearate microcrystalline cellulose <u>Film-coating:</u> polyvinyl alcohol, macrogol 3350, titanium dioxide, purified talc, sunset yellow FCF aluminium lake.
Potential allergens	n/a

Do not take this medicine if you are allergic to any of these ingredients.

What Harvoni 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.

AUST R 222848.

Who distributes Harvoni

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 May 2022.

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