





**HARVONI®**  
ledipasvir/sofosbuvir  
90 mg/400 mg tablets



**GILEAD**

This booklet does not replace the Patient Information Leaflet (PIL) included in your medicinal pack. Please refer to the PIL for full information.

The dose referred to in this patient booklet is for adults only. Other doses should be used for paediatric patients. This material should only be given to adult patients.

**Reporting side effects:** If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report any side effects you may get directly via the Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. For Ireland, Reporting forms and information can be found at [www.hpra.ie](http://www.hpra.ie) and can be reported to HPRA on +353 1 6764971.

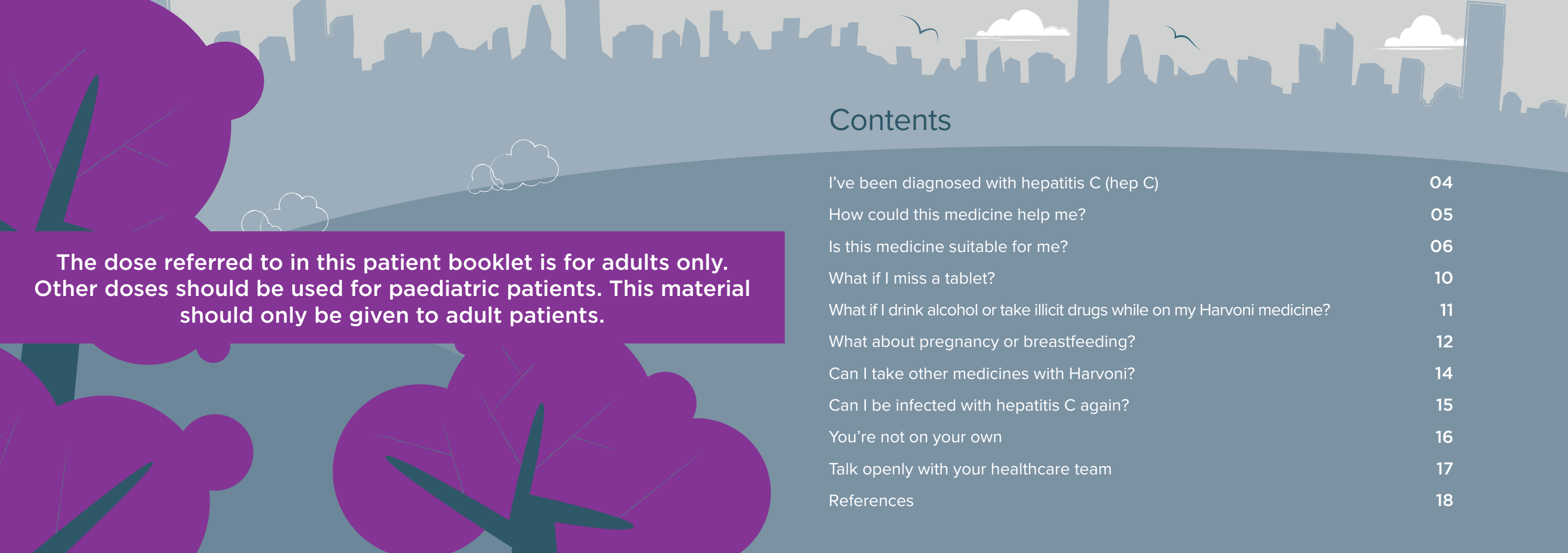
By reporting side effects, you can help provide more information on the safety of this medicine.

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**You and your  
medicine**

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# I've been diagnosed with hepatitis C

Hepatitis C (hep C) is a virus that can infect the liver.<sup>1</sup> The hepatitis C virus lives in infected blood (and other bodily fluids) and is most commonly spread when someone comes into contact with blood from an infected person.<sup>1,2</sup> Your diagnosis of hep C may have you feeling worried, but diagnosis is the first step in the journey to improving your health.

# How could this medicine help me?

Your healthcare provider has given you Harvoni to treat hepatitis C. As long as the medicine is taken in the recommended way, more than 90% of people may be cured.<sup>1,3-6</sup>



of patients with hep C may be cured.<sup>3-6</sup>

## What is the medicine I've been given?

Harvoni 90mg/400mg is an orange, diamond-shaped, film-coated tablet containing substances called ledipasvir and sofosbuvir. On one side it is stamped with the letters "GSI" and on the other side is the number "7985".<sup>3,4</sup>



Not to scale.

Medicines for hep C can sometimes cause side effects – headaches, rash or feeling tired. Swelling of the face, lips, tongue or throat may also be seen with Harvoni. Any side effects you have should settle down quickly. Your healthcare team should be able to suggest things to help ease any discomfort.<sup>3-5,7,8</sup>



Take one tablet, once a day for 12 or 24 weeks to help treat the virus, depending on how your doctor has advised you to take it.<sup>1,3-6</sup>

## Is this medicine suitable for me?

You and your healthcare team will have discussed the best treatment options for you. This might have included a discussion about your lifestyle as well as medicines that may suit you. If you have been given Harvoni, your healthcare team think it's an appropriate medicine for you.

Remember to tell your healthcare team about anything else you are taking – whether that's medicines, herbal remedies or illicit drugs.<sup>3,4,7,8</sup>

Harvoni is sometimes taken with another medicine, ribavirin. If you have any questions about your medicines, please ask your healthcare team.<sup>3,4,7-9</sup>

If for any reason you don't feel comfortable with the medicine you've been given, make sure you ask your healthcare team for more advice.

If you're in a sexual relationship you'll need some effective contraception for you and your partner while you're being treated for your hepatitis C infection, so ask for something suitable. This will minimise the risk of passing it on to your partner or an unborn child.

You should also tell your healthcare team if any of the following apply to you *before* you take your Harvoni medicine:<sup>7,8</sup>

- You have problems with your liver or if you are awaiting a liver transplant
- You are living with hepatitis B, or have had a previous hepatitis B infection
- You have any kidney problems, or if you are on kidney dialysis
- You're pregnant and/or breastfeeding
- You're receiving treatment for HIV
- You're taking, or have recently taken, any medications for heart conditions
- You have diabetes

Please refer to the PIL for further information.

## How do I take my Harvoni medicine?



Take one tablet, once a day, with or without food, depending on how your doctor has advised you to take it. The tablet should not be crushed, split, or dissolved, so make sure you swallow it whole. For the best chance of cure, it is important to take your medicine as instructed by your doctor.<sup>3,4,7,8</sup>



If, however, your doctor has prescribed you another medicine called a proton pump inhibitor (such as omeprazole, lansoprazole, rabeprazole, pantoprazole or esomeprazole), you should take your Harvoni at the same time as the proton pump inhibitor. Do not take the proton pump inhibitor before Harvoni.<sup>3,4,7,8</sup>

If you are taking an antacid, take it at least 4 hours before or at least 4 hours after Harvoni.<sup>3,4,7,8</sup>

If your doctor has prescribed an H2-antagonist (such as famotidine, cimetidine, nizatidine or ranitidine), it should be taken together with or staggered from Harvoni.<sup>3,4,7,8</sup>

Your healthcare team may ask you to come back in for a check-up after 12 or 24 weeks to check that the virus has been cleared from your body. They'll carry out a blood test to do this. In a small number of people the virus is not cleared after treatment. If you're one of these people, your healthcare team may suggest you try another medicine.<sup>6-8</sup>

Remember to read the Patient Information Leaflet for more details on how to take your medicine.



## How should I store my Harvoni medicine?



There are no special storage requirements for Harvoni, so no need to keep it in the fridge. Your medicine should be kept out of sight and reach of children and animals, and should not be used after the expiration date shown on the packaging.<sup>7,8</sup>

If the seal is broken or missing when you first open your Harvoni medicine, tell your healthcare team immediately. Always dispose of any unused medicine through your pharmacist. Do not share your medicine with anyone else.<sup>7,8</sup>


# What if I miss a tablet?

Try to take your medicine at the same time every day – it will help you to remember. For example, when you get up in the morning or when you clean your teeth.

It's very important that you complete the full course of treatment to give the medicine the best chance of working to treat the hep C virus infection. If you do forget and miss taking your medicine at any point during the 12 or 24 weeks, it's not ideal, but try not to worry – the information below can help you continue your treatment to clear the virus.


First of all, work out how long it is since you last took a tablet.

18 hours




If you notice **within 18 hours** of missing your dose, it's ok to take the tablet you missed straight away.<sup>7,8</sup>  
*Take your next tablet at your usual time and carry on as before.*<sup>7,8</sup>

If it's been **more than 18 hours** since you last took your Harvoni tablet, just miss that dose out.<sup>7,8</sup>  
*Simply take your next dose as normal.*<sup>7,8</sup>



It's important that you don't take a double dose (that's two doses close together in time) so try to keep track.<sup>7,8</sup>



If you've been distracted recently and have missed more than one dose, please inform your healthcare team.



What if I drink alcohol or take illicit drugs while on my Harvoni medicine?



If you think that you will take illicit drugs or drink alcohol while taking your medicine, it's important that you tell your healthcare team. They can support you, and are there to give you help and advice without judgement.



### What about pregnancy or breastfeeding?

Harvoni is not recommended for use during pregnancy. This is because we don't know much about how Harvoni might affect pregnant women.<sup>3,4,7,8</sup>

It is important not to breastfeed during treatment, since it is not known if the two active substances of the medicine pass into human breast milk.<sup>7,8</sup>

Make sure you tell your healthcare team if you're pregnant or will be breastfeeding during treatment. They'll be happy to chat with you about it.<sup>7,8</sup>

**Pregnancy and ribavirin:** Pregnancy must be avoided if Harvoni is taken together with ribavirin. It is very important that you read the "Pregnancy" section in the ribavirin package leaflet very carefully. Ribavirin can be very damaging to an unborn baby. Therefore, special precautions in sexual activity must be taken if there is any chance for pregnancy to occur. Please ask your doctor for an effective contraceptive method suitable for you.<sup>3,4,7-9</sup>

If you or your partner become pregnant during Harvoni and ribavirin treatment or in the months that follow, you must contact your doctor immediately.<sup>3,4,7-9</sup>







### Can I take other medicines with Harvoni?

If you're taking other medicines including any herbal remedies, you must tell your healthcare team.<sup>7,8</sup> This is because some things can interact with your medicine and may make it less effective or work in a different way.

This also includes discussing any contraception you might be taking. If you're in a sexual relationship, you should not risk passing the infection on to your partner or an unborn child before you're cured, so you'll need effective contraception while you're being treated for hepatitis C.<sup>3,4,7,8</sup>

It's important to mention everything – even if you only take it occasionally.



### I'm worried about side effects

Like any other medicine, there are some common side effects with Harvoni such as headache, feeling tired and rash.<sup>3,4,7,8</sup>

Swelling of the face, lips, tongue or throat may also be seen with Harvoni.<sup>7,8</sup>

If you notice any side effects or you have any other questions about taking your medicine, just ask your healthcare provider. They'll be very happy to answer your questions. Remember to read the Patient Information Leaflet for more details on how to take your medicine and how to report any adverse events.



### Can I transmit my infection while on treatment and be infected with hep C after being cured?

You can still spread hep C during your treatment, so it's important to take your Harvoni medicine for the whole length of treatment. Successfully treating hep C means that you cannot pass it on to other people anymore.<sup>1</sup> But even after you have finished treatment, you can catch hep C again.<sup>1</sup> To reduce the risk of catching hep C again or passing it on, avoid:<sup>2</sup>

- Sharing needles, syringes and other items used to take drugs
- Having unprotected sex – this includes men who have sex with men
- Sharing your razor or toothbrush



## You're not on your own

If you'd like support and advice at any stage of your journey, your healthcare team will be happy to help you.

**You can also speak to the patient organisation**  
**The Hepatitis C Trust in confidence on**  
**020 7089 6221 or email [helpline@hepctrust.org.uk](mailto:helpline@hepctrust.org.uk)**

## Talk openly with your healthcare team

If you have other thoughts or questions that aren't answered by this booklet, the best place to start is with your healthcare team – they are always ready to help you.

Try to be as open as you can with them so they can help you in the best way possible. If you'd like to ask some questions, but can't think of any, here are some common ones that could help you get started.

### When starting treatment

How do I take the treatment?

What do I need to know during treatment?

Is there anything I need to tell my healthcare team before taking my medicine?

How often do I need to see my healthcare team, and will they arrange the appointments for me?

How long before I'm cured?

### After treatment

How can I avoid getting hepatitis C again?

What support services are available to me and how do I get in touch with them?

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## Notes

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