

Package leaflet: Information for the user

Epclusa 200 mg/50 mg film-coated tablets sofosbuvir/velpatasvir

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Epclusa is and what it is used for
2. What you need to know before you take Epclusa
3. How to take Epclusa
4. Possible side effects
5. How to store Epclusa
6. Contents of the pack and other information

If Epclusa has been prescribed for your child, please note that all the information in this leaflet is addressed to your child (in this case please read “your child” instead of “you”).

1. What Epclusa is and what it is used for

Epclusa is a medicine that contains the active substances sofosbuvir and velpatasvir. Epclusa is given to treat chronic (long-term) hepatitis C virus infection in adults and children aged 3 years and older.

The active substances in this medicine work together by blocking two different proteins that the virus needs to grow and reproduce itself, allowing the infection to be permanently eliminated from the body.

It is very important that you also read the leaflets for the other medicines that you will be taking with Epclusa. If you have any questions about your medicines, please ask your doctor or pharmacist.

2. What you need to know before you take Epclusa

Do not take Epclusa

- **If you are allergic** to sofosbuvir, velpatasvir or any of the other ingredients of this medicine (listed in section 6 of this leaflet).

→ If this applies to you, **do not take Epclusa and tell your doctor immediately.**

- **If you are currently taking any of the following medicines:**
 - **rifampicin** and **rifabutin** (antibiotics used to treat infections, including tuberculosis);
 - **St. John’s wort** (herbal medicine used to treat depression);
 - **carbamazepine, phenobarbital** and **phenytoin** (medicines used to treat epilepsy and prevent seizures).

Warnings and precautions

Talk to your doctor if you:

- **have liver problems** other than from hepatitis C, for instance
 - **if you have** a current or previous infection with the **hepatitis B** virus, since your doctor may want to monitor you more closely;
 - **if you have had a liver transplant**
- **have kidney problems or if you are on kidney dialysis**, since Epclusa has not been fully tested in patients with some severe kidney problems;
- **are taking treatment for human immunodeficiency virus (HIV) infection**, since your doctor may want to monitor you more closely.

Talk to your doctor or pharmacist before taking Epclusa if:

- you currently take, or have taken in the last few months, the medicine amiodarone to treat irregular heartbeats, as it may result in a life-threatening slowing of your heart beat. Your doctor may consider different treatments if you have taken this medicine. If treatment with Epclusa is needed, you may require additional heart monitoring.
- you have diabetes. You may need closer monitoring of your blood glucose levels and/or adjustment of your diabetes medicine after starting Epclusa. Some diabetic patients have experienced low sugar levels in the blood (hypoglycaemia) after starting treatment with medicines like Epclusa.

Tell your doctor immediately if you currently take, or have taken in the last months any medicines for heart problems and during treatment you experience:

- slow or irregular heartbeat, or heart rhythm problems;
- shortness of breath or worsening of existing shortness of breath;
- chest pain;
- light-headedness;
- palpitations;
- near fainting or fainting.

Blood tests

Your doctor will test your blood before, during and after your treatment with Epclusa. This is so that:

- Your doctor can decide if you should take Epclusa and for how long;
- Your doctor can confirm that your treatment has worked and you are free of the hepatitis C virus.

Children and adolescents

Do not give this medicine to children under 3 years of age. The use of Epclusa in patients under 3 years of age has not been studied.

Other medicines and Epclusa

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Warfarin and other similar medicines called vitamin K antagonists are used to thin the blood. Your doctor may need to increase the frequency of your blood tests to check how well your blood can clot.

Your liver function may change with treatment of hepatitis C and therefore may affect other medications (e.g. medicines used to suppress your immune system, etc.). Your doctor may need to closely monitor these other medicines you are taking and make adjustments after starting Epclusa.

If you are not sure talk to your doctor or pharmacist.

Some medicines should not be taken with Epclusa.

- **Do not take with any other medicine that contains sofosbuvir, one of the active substances in Epclusa.**

Tell your doctor or pharmacist if you are taking any of the medicines below:

- **amiodarone** used to treat irregular heartbeats;
- **rifapentine** (antibiotic used to treat infections, including tuberculosis);
- **oxcarbazepine** (medicine used to treat epilepsy and prevent seizures);
- **tenofovir disoproxil fumarate** or any medicine containing tenofovir disoproxil fumarate, used to treat HIV infection and chronic hepatitis B;
- **efavirenz** used to treat HIV infection;
- **digoxin** used to treat heart conditions;
- **dabigatran** used to thin the blood;
- **modafinil** used to treat sleep disorders;
- **rosuvastatin** or **other statins** used to treat high cholesterol.

Taking Epclusa with any of these may stop your medicines from working properly, or make any side effects worse. Your doctor may need to give you a different medicine or adjust the dose of medicine you are taking. This change could be to Epclusa or another medicine you are taking.

- **Get advice from a doctor or pharmacist** if you take medicines used to treat **stomach ulcers, heartburn or acid reflux** as they can decrease the amount of velpatasvir in your blood. These medicines include:
 - antacids (such as aluminium/magnesium hydroxide or calcium carbonate). These should be taken at least 4 hours before or 4 hours after Epclusa;
 - proton pump inhibitors (such as omeprazole, lansoprazole, rabeprazole, pantoprazole and esomeprazole). Epclusa should be taken with food 4 hours before using a proton pump inhibitor.
 - H₂-receptor antagonists (such as famotidine, cimetidine, nizatidine or ranitidine). If you need high doses of these medicines your doctor may give you a different medicine instead or adjust the dose of the medicine you are taking.

These medicines can decrease the amount of velpatasvir 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.

Pregnancy and contraception

The effects of Epclusa during pregnancy are not known. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Epclusa is sometimes used together with ribavirin. Ribavirin can harm your unborn baby. It is therefore very important that you (or your partner) do not become pregnant during this treatment or for a period of time after completing treatment. You must read the “Pregnancy” section in the ribavirin package leaflet very carefully. Ask your doctor for effective contraception method suitable for you and your partner.

Breast-feeding

Do not breast-feed during treatment with Epclusa. It is not known whether sofosbuvir or velpatasvir, the two active substances of Epclusa, pass into human breast milk.

Driving and using machines

Epclusa should not affect your ability to drive or use any tools or machinery.

Epclusa contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take Epclusa

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Recommended dose

The recommended dose of Epclusa **in adults** is **one 400 mg/100 mg tablet once a day for 12 weeks**.

The recommended dose of Epclusa **in patients aged 3 to less than 18 years is based on weight**.

Take Epclusa as advised by your doctor.

Swallow the tablet(s) whole with or without food. Do not chew, crush or split the tablet as it has a very bitter taste.

If you are taking an antacid (medicines used to relieve heartburn), take it at least 4 hours before or at least 4 hours after Epclusa.

If you are taking a proton pump inhibitor (medicines used to reduce acid production), take Epclusa with food 4 hours before using a proton pump inhibitor.

If you are sick (vomit) after taking Epclusa it may affect the amount of Epclusa in your blood. This may make Epclusa work less well.

- If you are sick (vomit) **less than 3 hours after** taking Epclusa, take another dose.
- If you are sick (vomit) **more than 3 hours after** taking Epclusa, you do not need to take another dose until your next scheduled dose.

If you take more Epclusa than you should

If you accidentally take more than the recommended dose you should contact your doctor or nearest emergency department immediately for advice. Keep the tablet bottle with you so that you can easily describe what you have taken.

If you forget to take Epclusa

It is important not to miss a dose of this medicine.

If you do miss a dose, work out how long it is since you last took your Epclusa:

- **If you notice within 18 hours** of the time you usually take Epclusa, you must take the dose as soon as possible. Then take the next dose at your usual time.
- **If it's 18 hours or more** after the time you usually take Epclusa, wait and take the next dose at your usual time. Do not take a double dose (two doses close together).

Do not stop taking Epclusa

Do not stop taking this medicine 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 treat your hepatitis C virus infection.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common side effects

(may affect more than 1 in 10 people)

- vomiting (observed in paediatric patients aged 3 to < 6 years)

Common side effects

(may affect up to 1 in 10 people)

- rash

Uncommon side effects

(may affect up to 1 in 100 people)

- swelling of the face, lips, tongue or throat (angioedema).

Other effects that may be seen during treatment with sofosbuvir:

The frequency of the following side effects is not known (frequency cannot be estimated from the available data).

- 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).

→ If you get any side effects tell your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Epclusa

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle and carton after “EXP”. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Epclusa contains

- **The active substances are** sofosbuvir and velpatasvir. Each film-coated tablet contains either 400 mg sofosbuvir and 100 mg velpatasvir or 200 mg sofosbuvir and 50 mg velpatasvir.

- **The other ingredients are**

Tablet core:

Copovidone (E1208), microcrystalline cellulose (E460), croscarmellose sodium (E468) (see section 2 of this leaflet), magnesium stearate (E470b).

Film-coating:

Polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol, talc (E553b), iron oxide red (E172)

What Epclusa looks like and contents of the pack

Epclusa 400 mg/100 mg film-coated tablets are pink, diamond-shaped tablets debossed with “GSI” on one side and “7916” on the other side. The tablet is 20 mm long and 10 mm wide.

Epclusa 200 mg/50 mg film-coated tablets are pink, oval-shaped tablets debossed with “GSI” on one side and “S/V” on the other side. The tablet is 14 mm long and 7 mm wide.

The following pack sizes are available for both the 400 mg/100 mg and 200 mg/50 mg film-coated tablets:

- outer cartons containing 1 bottle of 28 film-coated tablets

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