

# EPCLUSA<sup>®</sup> Film-coated Tablets

Sofosbuvir 400mg / velpatasvir 100mg

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## 1. What Epclusa is used for

Epclusa is a medicine that contains the active substances sofosbuvir and velpatasvir in a single tablet. It is given to treat a chronic (long-term) viral infection of the liver called hepatitis C in adults of 18 years and older.

## 2. How Epclusa works

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.

Epclusa is sometimes taken with another medicine, ribavirin.

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.

## 3. Before you take Epclusa

### When you must not use it

#### **Do not take Epclusa**

- **If you are allergic** to sofosbuvir, velpatasvir or any of the other ingredients of this

medicine (listed in section 8 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).

### Before you start to use it

#### **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 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 (your doctor may consider alternative treatments if you have taken this medicine).

- you have diabetes. You may need closer monitoring of your blood glucose levels and/or adjustment of your diabetes medication 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 are taking any medicines for heart problems and during treatment you experience:

- shortness of breath
- light-headedness
- palpitations
- 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.

### Taking other medicines

#### **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 used to thin the blood. Your doctor may need to increase the frequency of

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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 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;
- **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.
- H<sub>2</sub>-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.

## Children and adolescents

Do not give this medicine to children and adolescents under 18 years of age. The use of Epclusa in children and adolescents has not yet been studied.

## 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.

## **4. 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.

## How much and how long to use it

### **Recommended dose**

The recommended dose is **one tablet once a day for 12 weeks.**

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

## When to use it

**If you are taking an antacid,** take it at least 4 hours before or at least 4 hours after Epclusa.

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

## 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 tablet 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).

## If you take more Epclusa than you should (overdose)

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.

## 5. While you are using it

### Things you must do

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

### Things you must not do

#### **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.

### Things to be careful of

#### **Driving and using machines**

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

## 6. Side effects

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

### **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.

Common side effects include headache, fatigue and nausea.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) (Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

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

## 7. Storage and Disposal of Epclusa

### Storage

Store below 30°C.

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.

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This medicine does not require any special storage conditions.

## Disposal

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.

## 8. Product Description

### What Epclusa looks like and contents of the pack

The film-coated tablets are pink, diamond-shaped tablets debossed with “GSI” on one side and “7916” on the other side.

The following pack size is available: outer cartons containing 1 bottle of 28 film-coated tablets

### What Epclusa contains

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

- **The other ingredients are**

*Tablet core:*

Copovidone,  
microcrystalline cellulose,  
croscarmellose sodium,  
magnesium stearate

*Film-coating:*

Polyvinyl alcohol,  
titanium dioxide,  
polyethylene glycol,  
talc, iron oxide red

### MAL Number

MAL18046002AZ

## 9. Manufacturer and Product Registration Holder

### Manufacturer

Gilead Sciences Ireland UC

IDA Business and Technology  
Park  
Carrigtohill  
Co. Cork  
Ireland

### Product Registration Holder

Gilead Sciences Malaysia Sdn  
Bhd  
Level 22, Axiata Tower  
9, Jalan Stesen Sentral 5  
Kuala Lumpur Sentral 50470  
Kuala Lumpur

## 10. Date of Revision

10/04/2020

### **Serial number**

NPRA (R1/2) 07042020/065

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