

EPCLUSA® Tablets

sofosbuvir/velpatasvir 400 mg/100 mg tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about EPCLUSA. 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 EPCLUSA 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 EPCLUSA is used for

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

Hepatitis C is a virus that infects the liver.

How EPCLUSA works

EPCLUSA is one tablet that contains two active substances, sofosbuvir and velpatasvir. 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.

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

EPCLUSA 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 EPCLUSA has been prescribed for you.

Use in children

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

Before you take EPCLUSA

When you must not take it

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

Do not take EPCLUSA if you are allergic to:

- sofosbuvir,
- velpatasvir, or
- any of the other ingredients of EPCLUSA. The ingredients of EPCLUSA are listed 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 EPCLUSA 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 EPCLUSA if you are taking any medicine other than EPCLUSA 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 EPCLUSA.

Do not take EPCLUSA 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 EPCLUSA 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 EPCLUSA on patients with severe kidney problems have not been fully tested.
- Have HIV infection
- 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. EPCLUSA 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 velpatasvir or sofosbuvir, the two active substances of EPCLUSA, 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 EPCLUSA.

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 EPCLUSA 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
- tenofovir disoproxil fumarate used to treat HIV infection
- efavirenz 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, phenobarbital, oxcarbazepine (medicines used to treat epilepsy and prevent seizures).
- Warfarin or other similar medicines called vitamin K antagonists used to thin the blood.

EPCLUSA may interact with these medicines. As a result, the amounts of EPCLUSA 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 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.

- 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. Your doctor may give you a different medicine or adjust the dose of medicine you are taking.
- 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 EPCLUSA. Do not start any new medicines while you are taking EPCLUSA 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 EPCLUSA.

How to take EPCLUSA

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

How much to take

The usual dose is one EPCLUSA 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

EPCLUSA tablets can be taken with or without food.

When to take it

Take EPCLUSA 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 EPCLUSA. If you forget to take EPCLUSA, 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 EPCLUSA 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 EPCLUSA 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: 13 11 26 (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 EPCLUSA tablets. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking EPCLUSA

Things you must do

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

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

Things you must not do

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

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

It is important not to stop taking your EPCLUSA 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 EPCLUSA affects you.

Side effects

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

EPCLUSA 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
- inflammation of nose and throat (nasopharyngitis)

Check with your doctor as soon as possible if you have any problems while taking EPCLUSA, 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 EPCLUSA

Storage

Keep EPCLUSA tablets where children cannot reach them.

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

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

Do not store EPCLUSA or any other medicine in a bathroom or near a sink.

Do not leave EPCLUSA in the car or on a window sill – heat and dampness can destroy some medicines.

Keep your EPCLUSA tablets in the bottle with the cap tightly closed until you take them.

If you take EPCLUSA 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

EPCLUSA tablets are diamond-shaped and pink in colour. Each tablet has “GSI” on one side and “7916” on the other side of the tablet.

EPCLUSA tablets are supplied in bottles containing 28 tablets.

Ingredients

Active Ingredients: sofosbuvir and velpatasvir

Inactive Ingredients: copovidone, microcrystalline cellulose croscarmellose sodium and magnesium stearate.

Film-coating: polyvinyl alcohol, macrogol 3350, titanium dioxide, talc-purified and iron oxide red.

Sponsor

Australia

Gilead Sciences Pty Ltd
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Melbourne, Victoria 3004

New Zealand

c/- Grant Thornton New Zealand Limited,
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This leaflet was prepared on March 2018

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