PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

EPCLUSA 400 mg/100 mg film-coated tablets

sofosbuvir/velpatasvir

Sugar-free

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- EPCLUSA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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 in a single tablet.
It is given to treat a chronic (long-term) viral infection of the liver called hepatitis C in patients aged 12 years and older and weighing at least 30 kg.

The active substances in Epclusa work together by blocking two different proteins that the virus needs to grow and reproduce itself, allowing for the containment and/or eradication of the infection.

EPCLUSA is sometimes taken with another medicine, ribavirin.

It is very important that you also read the patient information leaflets for the other medicines (e.g ribavirin) 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 Epclusa (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, rifapentine and rifabutin (used to treat tuberculosis);
- St. John's wort (herbal medicine used to treat depression);
- Carbamazepine, phenobarbital, phenytoin and oxcarbazepine (medicines used to treat epilepsy and prevent seizures);
- Efavirenz (for HIV infection), and modafinil (for excessive day time sleeping/narcolepsy)
- If you are treated with Epclusa, with or without ribavirin, and you are pregnant or planning to become pregnant or if you are breastfeeding your baby.
- All the "Do not Take" items listed in the ribavirin patient information leaflet (PIL) also apply to you when you are treated with Epclusa in combination with ribavirin.

Warnings and precautions

Talk to your doctor if you:

- have liver problems other than 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, 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 (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 patients have experienced high (hyperglycaemia) and/or low blood sugar levels (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
- a slow heart rate
- 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 contained and/or eradicated the virus.

Children and adolescents

Do not give Epclusa to children and adolescents under 12 years of age and weighing less than 30 kg. The use of EPCLUSA in patients under 12 years of age has not yet been established.

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 prevent blood clotting. 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 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.
- tenofovir disoproxil fumarate or any medicine containing tenofovir disoproxil fumarate, used to treat HIV infection;
- digoxin used to treat heart conditions;
- dabigatran used to prevent the formation of blood clots;
- rosuvastatin or other statins used to treat high cholesterol.

Taking EPCLUSA with any of these may stop your medicines from working properly, or make 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 (one of the active ingredients in Epclusa) 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_2-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

Do not take Epclusa during pregnancy as harm to your unborn baby cannot be excluded.

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 if your male partner is on treatment) 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 your baby during treatment with EPCLUSA. It is not known whether sofosbuvir or velpatasvir, the two active substances of EPCLUSA, pass into human breast milk. The active ingredients of Epclusa may harm your baby. **Do not breast-feed your baby if you are on treatment with Epclusa and ribavirin as your baby may be harmed.**

Driving and using machines

You should not drive and use machines until you know how treatment with Epclusa or Epclusa combined with ribavirin affects you.

3. How to take EPCLUSA

Do not share medicines prescribed for you with any other person. Always take Epclusa 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 is one 400 mg/100 mg tablet once a day for 12 weeks.

Swallow the tablet 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, 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 take more EPCLUSA than you should

If you accidentally take more than the recommended dose you should contact your doctor or nearest hospital 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 Epclusa.

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).

Do not stop taking EPCLUSA

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 Epclusa the best chance to treat your hepatitis C virus infection.

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

4. Possible side effects

EPCLUSA can have side effects. Not all side effects reported for EPCLUSA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking EPCLUSA, please consult your healthcare provider for advice.

Frequent side effects:

- Headache
- Tiredness (fatigue)

Less frequent side effects:

- Feeling sick (nausea)
- Diarrhoea
- Constipation
- Indigestion
- Stomach pain
- Vomiting
- Feeling bloated
- Feeling weak (asthenia)
- Common cold (nasopharyngitis)
- Lack of appetite
- Joint pain
- Muscle pain
- Muscle spasms
- Dizziness
- Disturbance in attention
- Inability to sleep (insomnia)
- Irritability
- Sleep disorder
- Depressed mood
- Shortness of breath

- Itchiness
- Rash
- Swelling of the face, lips, tongue or throat with difficulty to breathe (angioedema). **These are serious side effects. Seek urgent medical attention if you experience any of these symptoms.**

Other effects that may be seen during treatment:

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). **These are serious side effects. Seek urgent medical attention if you experience any of these symptoms.**

You should also read the patient information leaflet of ribavirin for side effects that you may experience if you are on treatment with Epclusa and ribavirin.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of EPCLUSA.

5. How to store EPCLUSA

Store all medicines out of reach of children

Do not use after the expiry date stated on the label / carton / bottle

The expiry date refers to the last day of that month.

Store at or below 30 °C

Keep the container tightly closed.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What EPCLUSA contains

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

The other ingredients include:

Tablet core: Copovidone, Microcrystalline cellulose, Croscarmellose sodium, Magnesium stearate

Film-coating: Polyvinyl alcohol, Titanium dioxide, Polyethylene glycol/ Macrogol 3350, Talc, Iron oxide Red and Iron Oxide Yellow.

What EPCLUSA looks like and contents of the pack

The film-coated tablets are red, diamond-shaped tablets debossed with

“GSI” on one side and “7916” on the other side.

The following pack sizes are available:

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

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