

Package leaflet: Information for the user

Vosevi 400 mg/100 mg/100 mg film-coated tablets sofosbuvir/velpatasvir/voxilaprevir

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

If Vosevi 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 Vosevi is and what it is used for

Vosevi is a medicine that contains the active substances sofosbuvir, velpatasvir and voxilaprevir 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 this medicine work together by blocking three different proteins that the hepatitis C virus needs to grow and reproduce itself, causing the infection to be eliminated from the body.

2. What you need to know before you take Vosevi

Do not take Vosevi

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

→ If this applies to you, **do not take Vosevi 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** (a herbal medicine used to treat depression);
 - **carbamazepine, phenobarbital** and **phenytoin** (medicines used to treat epilepsy and prevent seizures);
 - **rosuvastatin** (a medicine used to treat high blood cholesterol or decrease the risk of certain cardiovascular events);
 - **dabigatran** (a medicine used to prevent blood clots);
 - **ethinylestradiol** containing medicines, including many contraceptives.

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.**
- **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 Vosevi 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 alternative treatments if you have taken this medicine. If treatment with Vosevi 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 medication after starting Vosevi. Some diabetic patients have experienced low sugar levels in the blood (hypoglycaemia) after starting treatment with medicines like Vosevi.

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 Vosevi. This is so that:

- Your doctor can decide if you should take Vosevi 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 12 years of age and weighing less than 30 kg. The use of Vosevi in these patients has not yet been studied.

Other medicines and Vosevi

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

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

Some medicines must not be taken with Vosevi. Taking Vosevi with any of these may stop your medicines from working properly, or make any side effects worse:

- **rifampicin** and **rifabutin** (antibiotics used to treat infections, including tuberculosis);
- **St. John's wort** (a herbal medicine used to treat depression);
- **carbamazepine, phenobarbital** and **phenytoin** (medicines used to treat epilepsy and prevent seizures);
- **rosuvastatin** (a medicine used to treat high blood cholesterol or decrease the risk of certain cardiovascular events);

- **dabigatran** (a medicine used to prevent blood clots);
- **ethinylestradiol** containing medicines, including many contraceptives.

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

- **amiodarone**, used to treat irregular heartbeats;
- **rifapentine** (an 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;
- **atazanavir, efavirenz or lopinavir**, used to treat HIV infection;
- **digoxin**, used to treat heart conditions;
- **modafinil**, used to treat sleep disorders;
- **atorvastatin, pravastatin, or other statins**, used to treat high cholesterol;
- **ciclosporin**, used to suppress the immune system.

Taking Vosevi 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.

- **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 Vosevi;
 - proton pump inhibitors (such as omeprazole, lansoprazole, rabeprazole, pantoprazole and esomeprazole). 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;
 - 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 Vosevi 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.

- **Get advice from a doctor or pharmacist** if you take **warfarin or other similar medicines** called vitamin K antagonists 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 Vosevi.

Pregnancy, breast-feeding and fertility

If you are pregnant, think you may be pregnant, are breast-feeding your baby, or are planning to have a baby ask your doctor for advice before taking this medicine.

Pregnancy

Vosevi is not recommended during pregnancy. The effects of Vosevi during pregnancy are not known.

Breast-feeding

Do not breast-feed during treatment with Vosevi. Some of the active substances of Vosevi may pass into human breast milk.

Driving and using machines

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

Vosevi contains lactose

- **Tell your doctor if you are lactose intolerant or intolerant to other sugars.** Vosevi contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicinal product.

3. How to take Vosevi

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 Vosevi is **one 400 mg/100 mg/100 mg tablet or two 200 mg/50 mg/50 mg tablets, taken once a day for 8 or 12 weeks.**

Take Vosevi as advised by your doctor.

Swallow the tablet(s) whole with food. Do not chew, crush or split the tablet as it has a very bitter taste.

Kidney problems

Tell your doctor if you **have kidney problems** or if you are on **kidney dialysis**, since Vosevi has not been fully tested in patients with severe kidney problems.

Liver problems

Vosevi should not be used if you have moderate or severe liver problems.

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

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

- If you are sick (vomit) **less than 4 hours after** taking Vosevi, take another dose.
- If you are sick (vomit) **more than 4 hours after** taking Vosevi, you do not need to take another dose until your next scheduled dose.

If you take more Vosevi than you should

If you accidentally take more than the recommended dose of Vosevi you may be at increased risk of side effects with this medicine (*see section 4 Possible side effects*).

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 Vosevi

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 Vosevi:

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

Do not stop taking Vosevi

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 may cause side effects, although not everybody gets them.

Some side effects could be serious.

Stop taking Vosevi and seek medical help immediately if you experience any of the following symptoms:

- swelling of the face, lips, tongue or throat (angioedema) (*an uncommon side effect - may affect up to 1 in 100 people*)
- 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) (*the frequency of the side effect is not known*)

Other side effects that may occur

Very common side effects

(may affect more than 1 in 10 people)

- headache
- diarrhoea
- feeling sick (nausea)

Common side effects

(may affect up to 1 in 10 people)

- stomach pain
- decreased appetite
- being sick (vomiting)
- muscle pain (myalgia)
- abnormality in a laboratory test of liver function (total bilirubin)
- rash

Uncommon side effects

(may affect up to 1 in 100 people)

- muscle spasms

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 Vosevi

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 temperature storage conditions. Store in the original package in order to protect from moisture. Keep the bottle tightly closed.

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 Vosevi contains

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

- **The other ingredients are**

Tablet core:

Colloidal anhydrous silica, copovidone, croscarmellose sodium (E468), lactose monohydrate, magnesium stearate, microcrystalline cellulose (E460)

Film-coating:

Iron oxide black (E172), iron oxide red (E172), iron oxide yellow (E172), macrogol (E1521), polyvinyl alcohol (E1203), talc (E553b), titanium dioxide (E171)

What Vosevi looks like and contents of the pack

Vosevi 400 mg/100 mg/100 mg film-coated tablets are beige, capsule-shaped tablets debossed with “GSI” on one side and “3” on the other side. The tablet is 20 mm long and 10 mm wide.

The tablets are packed in plastic bottles with child resistant caps. Each bottle contains a silica gel desiccant (drying agent) that must be kept in the bottle to help protect your tablets. The silica gel desiccant is contained in a separate sachet or canister and should not be swallowed.

The following pack size is available:

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

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