EMA/417783/2017
EMEA/H/C/004350

EPAR summary for the public

Vosevi

sofosbuvir / velpatasvir / voxilaprevir

This is a summary of the European public assessment report (EPAR) for Vosevi. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Vosevi.

For practical information about using Vosevi, patients should read the package leaflet or contact their doctor or pharmacist.

What is Vosevi and what is it used for?

Vosevi is an antiviral medicine used to treat adults with chronic (long-term) hepatitis C, an infectious disease that affects the liver, caused by the hepatitis C virus (HCV).

Vosevi contains the active substances sofosbuvir, velpatasvir and voxilaprevir.

How is Vosevi used?

Vosevi can only be obtained with a prescription, and treatment should be started and monitored by a doctor experienced in the management of patients with hepatitis C virus infection.

Vosevi is available as tablets containing 400 mg sofosbuvir, 100 mg velpatasvir and 100 mg voxilaprevir. The recommended dose is one tablet taken once a day with food for 8 or 12 weeks. The duration of treatment depends on whether patients have liver cirrhosis (scarring of the liver) or have received treatment with other direct-acting antivirals.

For further information, see the package leaflet.

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How does Vosevi work?

The active substances in Vosevi (sofosbuvir, velpatasvir and voxilaprevir) block three proteins essential for the hepatitis C virus to multiply. Sofosbuvir blocks the action of an enzyme (a type of protein) called 'NS5B RNA-dependent RNA polymerase', velpatasvir targets a protein called 'NS5A', while voxilaprevir blocks an enzyme called NS3/4A protease. By blocking these proteins, Vosevi stops the hepatitis C virus from multiplying and infecting new cells.

Sofosbuvir/velpatasvir has been authorised in the EU as Epclusa since July 2016.

What benefits of Vosevi have been shown in studies?

Vosevi has been shown in four main studies of 1,459 patients to be effective at clearing all six varieties (genotypes) of the hepatitis C virus, including in patients with liver cirrhosis and those who have previously tried other direct-acting antivirals.

The clearance rates with Vosevi were typically above 95%. Over 96% of patients taking Vosevi in one study tested negative for HCV (their blood tests did not show any sign of the virus) after 12 weeks of treatment, compared with none of the patients who received placebo (a dummy treatment). Over 97% of patients taking Vosevi in a second study tested negative, compared with 90% of patients taking only sofosbuvir/velpatasvir. In two further studies between 95 and 96% of Vosevi patients tested negative for the virus, compared with 96 to 98% of patients taking sofosbuvir/velpatasvir.

What are the risks associated with Vosevi?

The most common side effects with Vosevi (which may affect more than 1 in 10 people) are headache, nausea (feeling sick) and diarrhoea.

Vosevi must not be used together with certain medicines such as:

- rosuvastatin (medicine for lowering cholesterol in the blood);
- dabigatran etexilate (medicine for preventing blood clots);
- ethinyl oestradiol-containing products (such as contraceptive medicines);
- rifampicin, rifabutin (antibiotics usually used to treat tuberculosis);
- carbamazepine, phenobarbital, phenytoin (medicines for epilepsy);
- St John's wort (a herbal remedy used for depression and anxiety).

For the full list of side effects and restrictions with Vosevi, see the package leaflet.

Why is Vosevi approved?

Vosevi has been shown to be highly effective in clearing the hepatitis C virus of all genotypes from the blood of patients (both previously treated and untreated) or who have cirrhosis. The fact that Vosevi can be given for 8 weeks (instead of the usual 12) to patients who do not have liver cirrhosis is considered an advantage. Additionally, Vosevi was shown to be very effective at eliminating the hepatitis C virus in patients in whom previous treatment with a NS5A inhibitor failed. Regarding safety, Vosevi was well tolerated with no major safety concern emerging.

The European Medicines Agency therefore decided that Vosevi's benefits are greater than its risks and recommended that it be approved for use in the EU.

What measures are being taken to ensure the safe and effective use of Vosevi?

The company that markets Vosevi will carry out a study in patients who previously have had liver cancer to evaluate the risk of liver cancer returning after treatment with direct-acting antivirals. This study is being carried out in light of data suggesting that patients treated with medicines belonging to the same class as Vosevi who have had liver cancer could be at risk of their cancer returning early.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Vosevi have also been included in the summary of product characteristics and the package leaflet.

Other information about Vosevi

The European Commission granted a marketing authorisation valid throughout the European Union for Vosevi on 26 July 2017.

The full EPAR for Vosevi can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Vosevi, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2017.