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Vosevi (sofosbuvir / velpatasvir / voxilaprevir)

An overview of Vosevi and why it is authorised in the EU

What is Vosevi and what is it used for?

Vosevi is an antiviral medicine used to treat chronic hepatitis C, an long-term infection of the liver caused by the hepatitis C virus (HCV), in patients aged 12 and older, weighing at least 30 kg.

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 HCV infection.

Vosevi is available as tablets containing 400 mg sofosbuvir, 100 mg velpatasvir and 100 mg voxilaprevir or 200 mg sofosbuvir, 50 mg velpatasvir and 50 mg voxilaprevir. The recommended dose is one 400 mg/100 mg/100 mg tablet or two 200 mg/50 mg/50 mg tablets 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 more information about using Vosevi, see the package leaflet or contact your healthcare provider.

How does Vosevi work?

The active substances in Vosevi (sofosbuvir, velpatasvir and voxilaprevir) block three proteins essential for HCV 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 HCV from multiplying and infecting new cells.

What benefits of Vosevi have been shown in studies?

Vosevi has been shown in four main studies of 1,459 adults to be effective at clearing all six varieties (genotypes) of HCV, 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

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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.

For adolescents aged 12 to 18, another study showed that HCV was not detected in the blood of any one of the 21 participants who were given Vosevi for 8 weeks, at 12 and 24 weeks after treatment.

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 authorised in the EU?

Vosevi has been shown to be highly effective in clearing HCV of all genotypes from the blood of both previously treated and untreated patients, including patients 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 HCV 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 it can be authorised 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.

As for all medicines, data on the use of Vosevi are continuously monitored. Side effects reported with Vosevi are carefully evaluated and any necessary action taken to protect patients.

Other information about Vosevi

Vosevi received a marketing authorisation valid throughout the EU on 26 July 2017.

Further information on Vosevi can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/vosevi.

This overview was last updated in 08-2021.