



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Epclusa (sofosbuvir / velpatasvir)

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

What is Epclusa and what is it used for?

Epclusa is an antiviral medicine used to treat patients from 3 years of age with chronic (long-term) hepatitis C, an infectious disease that affects the liver, caused by the hepatitis C virus. Hepatitis C virus occurs in several varieties (genotypes), and Epclusa can be used to treat hepatitis C caused by all genotypes of the virus.

Epclusa contains the active substances sofosbuvir and velpatasvir.

How is Epclusa used?

Epclusa can only be obtained with a prescription and treatment should be started and monitored by a doctor experienced in the management of patients with chronic hepatitis C.

Epclusa is available as tablets and as granules in a sachet for small children or those who have difficulties swallowing tablets. The recommended dose in adults is one tablet (containing 400 mg sofosbuvir and 100 mg velpatasvir) taken once a day for 12 weeks. In children, the dose of tablets or granules depends on body weight.

Epclusa is taken with another medicine called ribavirin in adults with decompensated liver disease (when the liver is not working properly). The addition of ribavirin to Epclusa may also be considered for adults who have compensated liver cirrhosis (scarring of the liver but the liver is still able to work adequately) and are infected with genotype 3 hepatitis C virus, a variety which is more difficult to treat.

For more information about using Epclusa, see the package leaflet or contact your doctor or pharmacist.

How does Epclusa work?

The active substances in Epclusa, sofosbuvir and velpatasvir, block two proteins essential for the hepatitis C virus to multiply. Sofosbuvir blocks the action of an enzyme called 'NS5B', while velpatasvir

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targets a protein called 'NS5A'. By blocking these proteins, Epclusa stops the hepatitis C virus from multiplying and infecting new cells.

Sofosbuvir has been authorised as Sovaldi since January 2014.

What benefits of Epclusa have been shown in studies?

In adults, Epclusa has been investigated in three main studies involving a total of 1,446 patients infected with hepatitis C (genotypes 1 to 6) with adequately working liver, some of whom had compensated liver disease (when the liver is damaged but works normally). In all three studies, the main measure of effectiveness was the number of patients whose blood tests did not show any sign of hepatitis C virus 12 weeks after the end of treatment. Looking at the results of the studies together, 98% of patients (1,015 out of 1,035) taking Epclusa for 12 weeks tested negative for the virus 12 weeks after the end of treatment.

An additional study was carried out in 267 hepatitis C patients whose liver was not working properly (Child-Pugh class B cirrhosis). Results showed that patients treated for 12 weeks with Epclusa in combination with ribavirin obtained the best results, with around 94% of patients (82 out of 87) testing negative for the virus 12 weeks after the end of treatment. This compared with 84% of patients who were treated with Epclusa alone.

A study in 173 children from 6 years of age showed that around 94% of patients tested negative for the virus 12 weeks after the end of treatment. Study results in another 41 children aged 3 to 5 years showed that around 83% of patients tested negative for the virus 12 weeks after the end of treatment.

What are the risks associated with Epclusa?

Epclusa must not be used together with the following medicines, as they may reduce the levels of sofosbuvir and velpatasvir in the blood and thereby reduce the effectiveness of Epclusa:

- rifampicin, rifabutin (antibiotics);
- carbamazepine, phenobarbital, phenytoin (medicines for epilepsy);
- St John's wort (a herbal preparation used for depression and anxiety).

For the full list of side effects or restrictions with Epclusa, see the package leaflet.

Why is Epclusa authorised in the EU?

Epclusa on its own has been shown to be highly effective in clearing the hepatitis C virus from the blood of patients whose liver is able to work adequately. Clearance of the virus was seen for all genotypes, including genotype 3. Clearance was also very high in patients whose liver is not working properly (Child-Pugh class B cirrhosis) when treated with Epclusa in combination with ribavirin. Epclusa was well tolerated with a favourable safety profile.

The European Medicines therefore decided that Epclusa'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 Epclusa?

The company that markets Epclusa will conduct a study to evaluate the recurrence of liver cancer in patients treated with the medicine.

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

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

Other information about Epclusa

Epclusa received a marketing authorisation valid throughout the EU on 6 July 2016.

Further information on Epclusa can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/epclusa

This overview was last updated in 12-2021.