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EPAR summary for the public

Epclusa

sofosbuvir / velpatasvir

This is a summary of the European public assessment report (EPAR) for Epclusa. 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 Epclusa.

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

What is Epclusa and what is it used for?

Epclusa 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.

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 which contain 400 mg sofosbuvir and 100 mg velpatasvir. Hepatitis C virus occurs in several varieties (genotypes) and Epclusa can be used to treat hepatitis C caused by all genotypes of the virus. The recommended dose is one tablet taken once a day for 12 weeks.

Epclusa is taken with another medicine called ribavirin in patients with decompensated liver disease (when the liver is not working properly). The addition of ribavirin to Epclusa may also be considered for patients 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 further information, see the summary of product characteristics (also part of the EPAR).

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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 RNA-dependent RNA polymerase', while velpatasvir 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?

Epclusa has been investigated in three main studies involving a total of 1,446 patients infected with hepatitis C (genotypes 1 to 6) whose liver was still able to work adequately but some of whom had compensated liver cirrhosis. 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.

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 approved?

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 Agency's Committee for Medicinal Products for Human Use (CHMP) therefore decided that Epclusa'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 Epclusa?

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

Other information about Epclusa

The European Commission granted a marketing authorisation valid throughout the European Union for Epclusa on 6 July 2016.

The full EPAR for Epclusa 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 Epclusa, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2016.