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EPAR summary for the public

Maviret

glecaprevir / pibrentasvir

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

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

What is Maviret and what is it used for?

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

Maviret contains the active substances glecaprevir and pibrentasvir.

How is Maviret used?

Maviret 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.

Maviret is available as tablets that contain 100 mg glecaprevir and 40 mg pibrentasvir. The recommended dose is three tablets once a day, with food, for 8, 12 or 16 weeks. The duration of treatment depends on whether patients have liver cirrhosis (scarring of the liver) or whether they have received previous treatments with pegylated interferon and ribavirin, with or without sofosbuvir, or sofosbuvir and ribavirin.

For further information, see the package leaflet.

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How does Maviret work?

The active substances in Maviret, glecaprevir and pibrentasvir, block two proteins essential for the hepatitis C virus to multiply. Glecaprevir blocks the action of a protein called NS3/4A protease, while pibrentasvir blocks a protein called NS5A. By blocking these proteins, Maviret stops the hepatitis C virus from multiplying and infecting new cells.

What benefits of Maviret have been shown in studies?

There are six varieties (genotypes) of the hepatitis C virus and Maviret has been shown to be effective at clearing all genotypes from the blood. In 8 main studies involving over 2,300 patients with hepatitis C, 99% of non-cirrhotic patients with genotype 1, the most common HCV genotype, tested negative for the virus after 8 weeks of Maviret treatment and 97% cirrhotic patients were negative after 12 weeks. A negative test result means that the virus was not found. Results were similar for genotypes 2 and 4-6. The medicine's effectiveness in clearing genotype 3 was slightly lower than for other genotypes (95%).

What are the risks associated with Maviret?

The most common side effects with Maviret (which may affect more than 1 in 10 people) are headache and tiredness.

Maviret must not be used in patients with severely reduced liver function. It must also not be used together with certain medicines such as:

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

For the full list of all restrictions and side effects reported with Maviret, see the package leaflet.

Why is Maviret approved?

Maviret has been shown to be highly effective in clearing the hepatitis C virus from the blood, particularly in patients who have not been treated previously or who do not have cirrhosis. The fact that Maviret can be given without ribavirin and without dose adjustments in patients with severe kidney problems is a further advantage in comparison with similar medicines. With regard to its safety, Maviret's pattern of side effects raises no particular concern.

The European Medicines Agency therefore decided that Maviret'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 Maviret?

The company that markets Maviret 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 such as Maviret. This study is being carried out in light of data suggesting that patients treated with medicines

belonging to the same class as Maviret and 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 Maviret have also been included in the summary of product characteristics and the package leaflet.

Other information about Maviret

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

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

This summary was last updated in 07-2017.