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Maviret *(glecaprevir / pibrentasvir)*

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

What is Maviret and what is it used for?

Maviret is an antiviral medicine used to treat adults and children from 3 years of age 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.

For adults, adolescents aged 12 and older, and children weighing at least 45 kg, Maviret is available as tablets that contain 100 mg glecaprevir and 40 mg pibrentasvir. The recommended dose is three tablets once a day. For children between 3 and 12 years old weighing between 12 and 45 kg, Maviret is available in sachets of granules that contain 50 mg glecaprevir and 20 mg pibrentasvir, with the recommended dose dependent on weight. Both tablets and granules should be taken with food and treatment lasts 8, 12 or 16 weeks.

The duration of treatment depends on the HCV variety (genotype), 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 (other medicines for hepatitis C).

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

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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 6 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 adults with hepatitis C, 99% of patients with genotype 1, the most common genotype, without cirrhosis, tested negative for the virus after 8 weeks of Maviret treatment and 97% patients with genotype 1 with cirrhosis were negative after 8 or 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%).

In a study in 47 children aged between 12 and 18 years with genotypes 1 to 4 and without cirrhosis, all patients tested negative for the virus after 12 weeks of treatment.

The same study investigated the use of Maviret in children between the ages of 3 and 11 without cirrhosis and with genotypes 1-4 of the hepatitis C virus. It showed that 98% of the 62 participants who received the final recommended dose tested negative after 8 weeks if they had not previously taken other treatments or after 12 to 16 weeks if they had previously been using interferon treatments.

Results in children also showed that the way the medicine was absorbed, modified and removed from the body was similar to that in adults. Based on data available in adults, it is expected that Maviret is also effective in children with genotypes 5 and 6.

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 (a 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 restrictions and side effects with Maviret, see the package leaflet.

Why is Maviret authorised in the EU?

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 it can be authorised 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.

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

Other information about Maviret

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

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

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