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EPAR summary for the public

Olysio

simeprevir

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

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

What is Olysio and what is it used for?

Olysio is an antiviral medicine that contains the active substance simeprevir. It is used to treat adults with chronic (long-term) hepatitis C, an infectious disease that affects the liver caused by the hepatitis C virus. Olysio is used in combination with other medicines.

How is Olysio used?

Olysio 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.

Olysio is available as 150 mg capsules. The recommended dose is one capsule taken once a day with food for 12 or 24 weeks. Olysio must be used in combination with other medicines used to treat chronic hepatitis C, such as with peginterferon alfa and ribavirin or with sofosbuvir.

Several varieties (genotypes) of hepatitis C virus exist and Olysio is recommended for patients with virus of genotypes 1 and 4. Before starting treatment with Olysio, patients with genotypes 1a should have a blood test to check whether the virus they are infected with has a mutation (a change in the genetic material of the virus) called Q80K, as Olysio is known to be less effective in these patients.

For further information, see the package leaflet.

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How does Olysio work?

The active substance in Olysio, simeprevir, blocks the action of an enzyme called 'NS3/4A serine protease' in the hepatitis C virus, which is essential for the virus to multiply. This stops the hepatitis C virus from multiplying and infecting new cells.

What benefits of Olysio have been shown in studies?

Several studies show that Olysio in combination with peginterferon alfa and ribavirin or with sofosbuvir is effective in clearing the hepatitis C virus from the blood after 12 or 24 weeks of treatment.

Three main studies involving 1,178 patients with hepatitis C virus of genotype 1 investigated the combination with peginterferon alfa and ribavirin. In two of the studies, which involved previously untreated patients, around 80% (419 out of 521) of patients taking Olysio tested negative for hepatitis C 12 weeks after the end of treatment, compared with 50% (132 out of 264) of patients on placebo.

In the third study, involving patients whose infections had come back following treatment with interferon-based therapy, around 80% (206 out of 260) of patients taking Olysio tested negative for hepatitis C 12 weeks after the end of treatment, compared with around 37% (49 out of 133) of patients on placebo.

An analysis of these studies showed that Olysio was less effective in a sub-group of patients infected with hepatitis C virus genotype 1a that has the Q80K mutation. Additional studies of the combination with peginterferon alfa and ribavirin involving patients with hepatitis C virus of genotype 4 and patients with HIV co-infection showed results consistent with those in patients with genotype 1.

Olysio taken together with sofosbuvir was investigated in a study involving 167 patients, which showed that the combination (with or without ribavirin) cleared infection with hepatitis C genotype 1 in around 90% of patients 12 weeks after the end of treatment. Prolonging treatment to 24 weeks resulted in a clearance rate of above 90%. The study included patients with and without cirrhosis as well as patients who had not responded to previous therapy.

In two additional studies of simeprevir in combination with sofosbuvir in 413 patients, patients without cirrhosis who were taking Olysio together with sofosbuvir had a clearance rate at 12 weeks of 97%, while patients with cirrhosis had a 12 weeks clearance rate of 83%.

What are the risks associated with Olysio?

The most common side effects during treatment with Olysio (which may affect more than 1 in 10 people) are nausea (feeling sick), rash, pruritus (itching) and dyspnoea (difficulty breathing). For the full list of side effects and restrictions, see the package leaflet.

Why is Olysio approved?

The European Medicines Agency decided that Olysio's benefits are greater than its risks and recommended that it be approved for use in the EU. The Agency concluded that, in both previously untreated patients and patients who had already been treated, adding Olysio to treatment with peginterferon alfa and ribavirin considerably increased the number of patients showing no sign of infection. The Agency also considered that the data available support the use of Olysio in combination with sofosbuvir. Regarding its safety, Olysio was well tolerated and the side effects were manageable.

What measures are being taken to ensure the safe and effective use of Olysio?

The company that markets Olysio 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 Olysio. This study is being carried out in light of data suggesting that patients treated with these medicines 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 Olysio have also been included in the summary of product characteristics and the package leaflet.

Other information about Olysio

The European Commission granted a marketing authorisation valid throughout the European Union for Olysio on 14 May 2014.

The full EPAR and risk management plan summary for Olysio 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 Olysio, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2017.