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EPAR summary for the public

Incivo

telaprevir

This is a summary of the European public assessment report (EPAR) for Incivo. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Incivo.

What is Incivo?

Incivo is a medicine that contains the active substance telaprevir. It is available as tablets (375 mg).

What is Incivo used for?

Incivo is used to treat chronic (long-term) hepatitis C (a disease of the liver due to infection with the hepatitis C virus) in combination with two other medicines, peginterferon alfa and ribavirin.

It is used in adults who have compensated liver disease (when the liver is damaged but is still functioning normally) including cirrhosis (scarring of the liver) either in previously untreated patients or in those who have already been treated with interferon alfa.

The medicine can only be obtained with a prescription.

How is Incivo used?

Treatment with Incivo should be started and monitored by a doctor experienced in managing chronic hepatitis C infections.

Three Incivo tablets should be swallowed whole twice a day with food for a period of 12 weeks. Alternatively, two Incivo tablets can be taken every eight hours with food. Treatment with ribavirin and peginterferon alfa will continue for a longer period, based on whether the patient has been treated before and test results during their Incivo treatment.

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How does Incivo work?

The active substance in Incivo, telaprevir, is a protease inhibitor. It blocks the action of an enzyme called NS3-4A protease in the hepatitis C virus, which is essential for its life cycle. This stops the hepatitis C virus from replicating in the infected host cells of the body. When Incivo is added to peginterferon alfa and ribavirin (the current standard treatment for hepatitis C) this increases the likelihood of the virus being killed.

How has Incivo been studied?

Incivo was investigated in three main studies in patients infected with hepatitis C. The first study involved 1,095 previously untreated patients, and the second study involved 663 patients who had already been treated with peginterferon alfa and ribavirin but were still infected. Both studies compared Incivo with placebo (a dummy treatment) added to a course of peginterferon alfa and ribavirin. A third study in previously untreated patients compared the effects of giving peginterferon alfa and ribavirin for different lengths of time (either six months or one year) together with three months of Incivo treatment. 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 six months after the end of treatment.

What benefit has Incivo shown during the studies?

In the first study, when Incivo was given for three months, 75% of patients tested negative for hepatitis C compared with 44% of patients receiving placebo. In the second study, 88% of patients receiving Incivo for three months tested negative for hepatitis C compared with 24% of patients receiving placebo. The third study showed that in patients treated with Incivo, giving peginterferon alfa and ribavirin for six months was as effective as giving these medicines for one year, since 92% of patients receiving them for six months tested negative for hepatitis C compared with 88% of patients receiving them for one year.

What is the risk associated with Incivo?

The most common side effects with Incivo (seen in more than 1 patient in 10) are anaemia (low red blood cell counts), nausea (feeling sick), diarrhoea, vomiting, haemorrhoids (piles), proctalgia (anal pain), pruritus (itching) and rash. For the full list of all side effects reported with Incivo, see the package leaflet.

Incivo must not be used in patients who are hypersensitive (allergic) to telaprevir or any of the other ingredients. Incivo must not be given in combination with several other medicines, including those which are affected by or affect the CYP3A gene and Class Ia or III antiarrhythmics. For the full list of restrictions, see the package leaflet.

Why has Incivo been approved?

The CHMP considered that adding Incivo to standard treatment represents a major advance in treating the most common type of hepatitis C virus. The Committee noted that in both previously untreated patients and patients who had already been treated, adding Incivo to standard treatment considerably increased the number showing no sign of infection after six months. In addition, treatment could be shortened for many patients and the benefits could be seen across different patient types with different degrees of liver damage.

The Committee noted that the main risks identified were severe rash and the possibility of the virus developing drug resistance, but considered that these risks were manageable. The CHMP therefore concluded that the benefits of Incivo were greater than its risks, and recommended it be granted marketing authorisation.

What measures are being taken to ensure the safe use of Incivo?

The company that markets Incivo will provide all doctors who are expected to prescribe it with an educational pack containing important safety information on the main risks with Incivo, in particular the risk of rash and severe skin reactions.

Other information about Incivo

The European Commission granted a marketing authorisation valid throughout the European Union for Incivo on 19 September 2011.

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

This summary was last updated in 06-2013.