EMA/431387/2011
EMEA/H/C/002332

EPAR summary for the public

Victrelis

boceprevir

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

What is Victrelis?

Victrelis is a medicine that contains the active substance boceprevir. It is available as capsules (200 mg).

What is Victrelis used for?

Victrelis is used to treat adults with chronic (long-term) hepatitis C genotype 1 (a disease of the liver due to infection with the hepatitis C virus) in combination with two other medicines, peginterferon alfa and ribavirin.

Victrelis is to be used in patients with compensated liver disease who have not been treated before or whose previous treatment has failed. Compensated liver disease is when the liver is damaged but is still able to work normally.

The medicine can only be obtained with a prescription.

How is Victrelis used?

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

The recommended dose is four capsules three times a day (a total of 12 capsules a day). It should be taken with food (a meal or light snack). If taken without food the medicine may not work properly.

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The patients must first take peginterferon alfa and ribavirin for four weeks, after which they will add Victrelis to the treatment for up to 44 weeks, depending on several factors such as the patient's previous treatment and results of blood tests during treatment. For more information on how to use Victrelis, including its combination with peginterferon alfa and ribavirin and the length of treatment, see the summary of product characteristics (also part of the EPAR).

How does Victrelis work?

The active substance in Victrelis, boceprevir, is a protease inhibitor. It blocks an enzyme called HCV NS3 protease, which is found on the hepatitis C virus of the type 1 genotype and is involved in the virus's replication. When the enzyme is blocked, the virus does not replicate normally and this slows down the rate of replication, helping to eliminate the virus.

How has Victrelis been studied?

The effects of Victrelis were first tested in experimental models before being studied in humans.

Two main studies involving 1,099 previously untreated and 404 previously treated patients with chronic hepatitis C genotype 1 infection and compensated liver disease were carried out. In both studies Victrelis was compared with placebo (a dummy treatment). All patients also received peginterferon alfa and ribavirin. The main measure of effectiveness was the number of patients who had no detectable virus in their blood 24 weeks after the end of the treatment and could therefore be considered to be cured.

What benefit has Victrelis shown during the studies?

Victrelis was effective at curing patients with chronic hepatitis C genotype 1 infection who were also treated with peginterferon alfa and ribavirin. In the study of previously untreated patients, 66% of patients who received Victrelis for 44 weeks (242 out 366) were cured compared with 38% of those who received placebo (137 out of 363).

In a second study in patients in whom previous treatment had failed, the cure rate was 67% (107 out of 161) for patients who received Victrelis for 44 weeks compared with 21% (17 out of 80) for those receiving placebo.

Victrelis was also shown to be effective in some patients whose treatment was shortened following blood tests in which the virus could no longer be detected in their blood.

What is the risk associated with Victrelis?

Victrelis in combination with peginterferon alfa and ribavirin can lead to a higher rate of anaemia (low red blood cell counts) than is seen in treatment with peginterferon and ribavirin alone. The other most common side effects with Victrelis are fatigue (tiredness), nausea (feeling sick), headache and dysgeusia (taste disturbances). For the full list of all side effects reported with Victrelis, see the package leaflet.

Victrelis must not be used in people who are hypersensitive (allergic) to boceprevir or any of the other ingredients. It must not be used in patients with autoimmune hepatitis (hepatitis caused by an immune disorder) or in pregnant women. Victrelis can slow down the rate at which certain medicines are broken down in the liver. These medicines can be harmful at high levels in the blood and it is important to avoid taking them when taking Victrelis. For a list of these medicines see the summary of product characteristics (also part of the EPAR).

Why has Victrelis been approved?

The CHMP noted that Victrelis in combination with peginterferon alfa and ribavirin significantly increases the number of patients cured of chronic hepatitis C infection. This was an important improvement on results seen with only peginterferon alfa and ribavirin together. The main increase in side effects seen when adding Victrelis to treatment was anaemia. However, the Committee decided that the medicine's benefits outweighed its risk and recommended that it be granted marketing authorisation.

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

The company that makes Victrelis will ensure that all doctors expected to prescribe the medicine are provided with an educational pack with detailed information on the medicine, including information on the risk of anaemia and other side effects.

Other information about Victrelis

The European Commission granted a marketing authorisation valid throughout the European Union for Victrelis on 18 July 2011.

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

This summary was last updated in 07-2012.