EMA/545960/2017
EMEA/H/C/004377

EPAR summary for the public

Entecavir Mylan

entecavir

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

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

What is Entecavir Mylan and what is it used for?

Entecavir Mylan is a medicine used to treat chronic (long-term) hepatitis B (an infectious disease of the liver, caused by the hepatitis B virus).

It is used in adults with signs of ongoing liver injury (such as inflammation and fibrosis) when the liver is still working properly (compensated liver disease) and also when the liver is no longer working properly (decompensated liver disease).

It can also be considered for children aged from 2 to 18 years but only in those with compensated liver disease.

Entecavir Mylan contains the active substance entecavir and is a 'generic medicine'. This means that Entecavir Mylan contains the same active substance and works in the same way as a 'reference medicine' already authorised in the European Union (EU) called Baraclude. For more information on generic medicines, see the question-and-answer document here.

How is Entecavir Mylan used?

Entecavir Mylan can only be obtained with a prescription and is available as tablets (0.5 mg and 1 mg). Treatment with Entecavir Mylan should be started by a doctor with experience in the management of chronic hepatitis B.

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Entecavir Mylan is taken once a day. For adults with compensated liver disease, the dose depends on whether or not the patient has been previously treated with a medicine in the same group as Entecavir Mylan (a nucleoside analogue, such as lamivudine). Patients who have not been treated before with a nucleoside analogue receive a 0.5 mg dose, while those who have received lamivudine before but whose infection is no longer responding to it are given a 1 mg dose. The 0.5 mg dose can be taken with or without food, but the 1 mg dose must be taken at least 2 hours before or 2 hours after a meal. The treatment duration is determined by how the patient responds.

The 1 mg daily dose is also used in adults with decompensated liver disease and stopping treatment is not recommended in these patients.

When treatment is considered appropriate in children, the dose depends on their body weight. Children weighing 32.6 kg and above can be given the 0.5 mg tablets, while an oral solution of entecavir should be used for children weighing less than 32.6 kg. For further information, see the package leaflet.

How does Entecavir Mylan work?

The active substance in Entecavir Mylan, entecavir, is an antiviral belonging to the class of the nucleoside analogues. Entecavir interferes with the action of a viral enzyme, DNA polymerase, which is involved in the formation of viral DNA. Entecavir stops the virus making DNA, and prevents it from multiplying and spreading.

How has Entecavir Mylan been studied?

Studies on the benefits and risks of the active substance in the approved uses have already been carried out with the reference medicine, Baraclude, and do not need to be repeated for Entecavir Mylan.

As for every medicine, the company provided studies on the quality of Entecavir Mylan. The company also carried out a study that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of Entecavir Mylan?

Because Entecavir Mylan is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Entecavir Mylan approved?

The European Medicines Agency concluded that, in accordance with EU requirements, Entecavir Mylan has been shown to have comparable quality and to be bioequivalent to Baraclude. Therefore, the Agency's view was that, as for Baraclude, the benefit outweighs the identified risk. The Agency recommended that Entecavir Mylan be approved for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Entecavir Mylan have been included in the summary of product characteristics and the package leaflet.

Other information about Entecavir Mylan

The European Commission granted a marketing authorisation valid throughout the European Union for Entecavir Mylan on 18 September 2017.

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

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 09-2017.