EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Entecavir Accord

entecavir

Table of contents

AUTHORISED
This medicine is authorised for use in the European Union.

Overview

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

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

What is Entecavir Accord and what is it used for?

Entecavir Accord 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 Accord contains the active substance entecavir and is a 'generic medicine'. This means that Entecavir Accord contains the same active substance and works in the same way as a 'reference medicine' already authorised in the European Union (EU) called Baraclude.

How is Entecavir Accord used?

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

Entecavir Accord 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 Accord (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 may be available for children weighing less than 32.6 kg. For further information, see the package leaflet.

How does Entecavir Accord work?

The active substance in Entecavir Accord, 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 Accord 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 Accord.

As for every medicine, the company provided studies on the quality of Entecavir Accord. 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 Accord?

Because Entecavir Accord 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 Accord approved?

The European Medicines Agency concluded that, in accordance with EU requirements, Entecavir Accord 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 Accord be approved for use in the EU.

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

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

package leaflet.

Other information about Entecavir Accord

The European Commission granted a marketing authorisation valid throughout the European Union for Entecavir Accord on 26 September 2017.

For more information about treatment with Entecavir Accord, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

Entecavir Accord : EPAR - Summary for the public (PDF/93.1 KB)

First published: 26/01/2018
Last updated: 26/01/2018

Available languages (22)

This EPAR was last updated on 29/07/2022

Authorisation details

Name
Entecavir Accord
Agency product number
EMEA/H/C/004458
Active substance
Entecavir
International non-proprietary name (INN) or common name
entecavir
Therapeutic area (MeSH)
Hepatitis B, Chronic
Anatomical therapeutic chemical (ATC) code
J05AF10
Generic Ⓖ

This is a generic medicine, which is developed to be the same as a medicine that has already been authorised, called the reference medicine. A generic medicine contains the same active substance(s) as the reference medicine, and is used at the same dose(s) to treat the same disease(s). For more information, see Generic and hybrid medicines.

Marketing-authorisation holder
Accord Healthcare S.L.U.
Revision
5
Date of issue of marketing authorisation valid throughout the European Union
25/09/2017
Contact address

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Product information

01/07/2022 Entecavir Accord - EMEA/H/C/004458 - R/0011

Entecavir Accord : EPAR - Product Information (PDF/364.7 KB)

First published: 26/01/2018
Last updated: 29/07/2022

Available languages (24)

This medicine's product information is available in all **official EU languages**.
Select 'available languages' to access the language you need.

Product information documents contain:

- summary of product characteristics (annex I);
- manufacturing authorisation holder responsible for batch release (annex IIA);
- conditions of the marketing authorisation (annex IIB);
- labelling (annex IIIA);
- package leaflet (annex IIIB).

You can find product information documents for centrally authorised human medicines on this website. For centrally authorised veterinary medicines authorised or updated from February 2022, see the Veterinary Medicines Information website.

Entecavir Accord : EPAR - All Authorised presentations (PDF/16.02 KB)

First published: 26/01/2018
Last updated: 26/01/2018

Available languages (24)

Pharmacotherapeutic group

Antivirals for systemic use

Therapeutic indication

Entecavir Accord is indicated for the treatment of chronic hepatitis B virus (HBV) infection in adults with:

- compensated liver disease and evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis.
- decompensated liver disease.

For both compensated and decompensated liver disease, this indication is based on clinical trial data in nucleoside naive patients with HBeAg positive and HBeAg negative HBV infection. With respect to patients with lamivudine-refractory hepatitis B.

Entecavir Accord is also indicated for the treatment of chronic HBV infection in nucleoside naive paediatric patients from 2 to <18 years of age with compensated liver disease who have evidence of active viral replication and persistently elevated serum ALT levels, or histological evidence of moderate to severe inflammation and/or fibrosis. With respect to the decision to initiate treatment in paediatric patients.

Assessment history

Changes since initial authorisation of medicine

Entecavir Accord : EPAR - Procedural steps taken and scientific information after the authorisation (PDF/108.23 KB)

First published: 13/11/2018
Last updated: 29/07/2022

Initial marketing-authorisation documents

Entecavir Accord : EPAR - Public assessment report (PDF/417.16 KB)

First published: 26/01/2018
Last updated: 26/01/2018
EMA/520001/2017

CHMP summary of positive opinion for Entecavir Accord (PDF/75.1 KB)

Adopted

First published: 21/07/2017
Last updated: 21/07/2017
EMA/CHMP/367264/2017

News

- Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 17-20 July 2017
  21/07/2017

More information on Entecavir Accord

Questions and answers on generic medicines (PDF/66.45 KB)

First published: 09/07/2007
Last updated: 07/12/2012
EMA/393905/2006 Rev. 2

Available languages (22)

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