LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Entecavir Medical Valley
entecavir monohydrate, entecavir (anhydrous)

SE/H/2201/01-02

This module reflects the scientific discussion for the approval of Entecavir Medical Valley. The Summary Public Assessment Report was written in August 2019 by the previous RMS (NL) after initial procedure NL/H/4408/001-002/DC. RMS transfer from NL to SE was completed 2021-12-07.

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Summary Public Assessment Report

Entecavir Medical Valley
entecavir monohydrate, entecavir (anhydrous)

Film-coated tablet, 0,5 mg, 1 mg

This is a summary of the public assessment report (PAR) for Entecavir Medical Valley. It explains how Entecavir Medical Valley was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Entecavir Medical Valley.

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

The summary of the public assessment report was written in August 2019 by the previous RMS NL after the initial procedure NL/H/4408/001-002/DC and is attached at the end of this document.

Summary Public Assessment Report

Generics

Entecavir Xiromed 0.5 mg and 1 mg, film-coated tablets

(entecavir)

NL/H/4408/001-002/DC

Date: 22 August 2019

Summary Public Assessment Report

Generics

Entecavir Xiromed 0.5 mg and 1 mg, film-coated tablets

Active substance: entecavir

This is a summary of the public assessment report (PAR) for Entecavir Xiromed 0.5 mg and 1 mg, film-coated tablets. It explains how this medicine was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Entecavir Xiromed.

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

What is Entecavir Xiromed and what is it used for?
Entecavir Xiromed is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Baraclude.

The medicine is 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.

How does this medicine work?
The active substance in this medicine, 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 is this medicine used?
The pharmaceutical form of Entecavir Xiromed is film-coated tablet and the route of administration is oral. The medicine can only be obtained with a prescription. Treatment with this medicine should be started by a doctor with experience in the management of chronic hepatitis B.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

How has this medicine been studied?
Because Entecavir Xiromed is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Baraclude. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of this medicine?
Because Entecavir Xiromed is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.
For the full list of all side effects reported with this medicine, see section 4 of the package leaflet.

Why is this medicine approved?
It was concluded that, in accordance with EU requirements, this medicine has been shown to have comparable quality and to be bioequivalent to the reference medicine. Therefore, the Medicines Evaluation Board of the Netherlands decided that, as for Baraclude, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of this medicine?
A risk management plan has been developed to ensure that this medicine is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Entecavir Xiromed, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about this medicine
In the Netherlands, the marketing authorisation for Entecavir Xiromed 0.5 mg and 1 mg, film-coated tablets was granted on 31 July 2019.

The full PAR for this medicine can be found on the website http://mri.cts-mrp.eu/Human. For more information about treatment with Entecavir Xiromed, read the package leaflet (http://mri.cts-mrp.eu/Human/Product/Details/57297) or contact your doctor or pharmacist.

This summary was last updated in August 2019.