EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Zeffix

lamivudine

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

Overview

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

What is Zeffix?

Zeffix is a medicine that contains the active substance lamivudine. It is available as tablets (100 mg) and an oral solution (5 mg/ml).

What is Zeffix used for?

Zeffix is used to treat adults (aged 18 years or over) who have chronic (long-term) hepatitis B (a disease of the liver due to infection with the hepatitis-B virus). It is used in patients with:

- compensated liver disease (when the liver is damaged but works normally), who also show signs that the virus is still multiplying and have signs of liver damage (raised levels of the liver enzyme alanine aminotransferase [ALT] and signs of damage when liver tissue is examined under a microscope). Because the hepatitis-B virus can become resistant to Zeffix, the doctor should only consider prescribing Zeffix if other treatments that are less likely to lead to resistance cannot be used;
- decompensated liver disease (when the liver does not work normally). To reduce the risk of resistance, Zeffix must be used in combination with another anti-hepatitis-B medicine that does not cause resistance in the same way as Zeffix.

The medicine can only be obtained with a prescription.

How is Zeffix used?

Treatment with Zeffix should be started by a doctor who has experience in the management of chronic hepatitis B.

The recommended dose of Zeffix is 100 mg once a day. The dose needs to be lower in patients who have reduced kidney function. Doses lower than 100 mg need to be given using the oral solution. The duration of treatment depends on the patient's condition and response to treatment.

If the hepatitis B virus can still be found in the blood after six months of treatment, the doctor should consider switching treatment or adding another medicine for hepatitis B to reduce the risk of resistance. For more information, see the summary of product characteristics (also part of the EPAR).

How does Zeffix work?

The active substance in Zeffix, lamivudine, is an antiviral agent that belongs to the class 'nucleoside analogues'. Lamivudine interferes with the action of a viral enzyme called DNA polymerase, which is involved in the formation of viral DNA. Lamivudine stops the virus making DNA and prevents it from multiplying and spreading.

How has Zeffix been studied?

Zeffix has been studied in five main studies involving a total of 1,083 adults with compensated liver disease due to chronic hepatitis B. Three studies compared Zeffix with placebo (a dummy treatment), one of which looked particularly at 'HBeAg-negative' patients. These are patients infected with hepatitis B virus that has mutated (changed), leading to a form of chronic hepatitis B that is more difficult to treat. The other two studies compared Zeffix taken on its own with alfa-interferon (another treatment used in chronic hepatitis B) on its own and with the combination of Zeffix and alfa-interferon.

In addition, information was presented on the use of Zeffix in patients with decompensated liver disease.

There were several measures of effectiveness in the studies. These included looking at how the liver damage had evolved after a year of treatment using a liver biopsy (when a small sample of liver tissue is taken and examined under a microscope), as well as measuring other signs of the disease such as the levels of ALT or of hepatitis B virus DNA circulating in the blood.

What benefit has Zeffix shown during the studies?

In patients with compensated liver disease, Zeffix was more effective than placebo in slowing down the progression of liver disease. About half of the patients taking Zeffix had an improvement in liver damage assessed in a biopsy, compared with about a quarter of the patients who took placebo. Zeffix was as effective as alfa-interferon.

In patients with decompensated liver disease, Zeffix also reduced levels of hepatitis B virus DNA and ALT.

What is the risk associated with Zeffix?

The most common side effect with Zeffix (seen in more than 1 patient in 10) is raised ALT levels. For the full list of all side effects or restrictions with Zeffix, see the package leaflet.

Why has Zeffix been approved?

The CHMP decided that Zeffix's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Zeffix

The European Commission granted a marketing authorisation valid throughout the European Union for Zeffix on 29 July 1999.

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

Zeffix : EPAR - Summary for the public (PDF/108.73 KB)

First published: 11/09/2009
Last updated: 06/06/2016

Available languages (22)

More detail is available in the summary of product characteristics

This EPAR was last updated on 10/02/2021

Authorisation details

Product details

Product details

Name	Zeffix
Agency product number	EMEA/H/C/000242
Active substance	lamivudine
International non-proprietary name (INN) or common name	lamivudine
Therapeutic area (MeSH)	Hepatitis B, Chronic
Anatomical therapeutic chemical (ATC) code	J05AF05

Publication details

Marketing-authorisation holder	GlaxoSmithKline (Ireland) Limited
Revision	26
Date of issue of marketing authorisation valid throughout the European Union	29/07/1999
Contact address	12 Riverwalk Citywest Business Campus Dublin 24 Ireland

Product information

25/01/2021 Zeffix - EMEA/H/C/000242 - IAIN/0080/G

Zeffix : EPAR - Product Information (PDF/485.92 KB)

First published: 02/09/2009
Last updated: 10/02/2021

Available languages (24)

Contents

Please note that the size of the above document can exceed 50 pages.

You are therefore advised to be selective about which sections or pages you wish to print.

Zeffix : EPAR - All Authorised presentations (PDF/62.31 KB)

First published: 07/08/2006
Last updated: 07/08/2006

Available languages (18)

Pharmacotherapeutic group

Antivirals for systemic use

Therapeutic indication

Zeffix is indicated for the treatment of chronic hepatitis B in adults with:

- compensated liver disease with evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active liver inflammation and / or fibrosis. Initiation of lamivudine treatment should only be considered when the use of an alternative antiviral agent with a higher genetic barrier is not available or appropriate;
- decompensated liver disease in combination with a second agent without cross-resistance to lamivudine.

Assessment history

Changes since initial authorisation of medicine

Zeffix : EPAR - Procedural steps taken and scientific information after authorisation (PDF/255.95 KB)

First published: 02/09/2009
Last updated: 10/02/2021

Zeffix-H-C-PSUSA/00001824/201507 : EPAR - Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s) (PDF/100.01 KB)

First published: 06/06/2016
Last updated: 06/06/2016
EMA/391172/2016

CHMP post-authorisation summary of positive opinion for Zeffix (PDF/66.8 KB)

Adopted

First published: 21/05/2010
Last updated: 21/05/2010

Zeffix : EPAR - Steps taken after authorisation when a cutoff date has been used (PDF/95.25 KB)

First published: 07/08/2006
Last updated: 07/08/2006

Initial marketing-authorisation documents

Zeffix : EPAR - Scientific Discussion (PDF/257.57 KB)

First published: 07/08/2006
Last updated: 07/08/2006

Zeffix : EPAR - Procedural steps taken before authorisation (PDF/95.54 KB)

First published: 07/08/2006
Last updated: 07/08/2006

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