EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Vemlidy

tenofovir alafenamide

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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 Vemlidy. 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 Vemlidy.

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

What is Vemlidy and what is it used for?

Vemlidy is an antiviral medicine for treating chronic (long-term) hepatitis B, an infectious disease that affects the liver.

This medicine is used in patients aged 12 years and older weighing at least 35 kg. It contains the active substance tenofovir alafenamide.

How is Vemlidy used?

Vemlidy is available as 25 mg tablets which are taken by mouth (one tablet a day) with food.The patient will usually take their medicine for at least 6 to 12 months, and treatment may last several years.

Vemlidy can only be obtained with a prescription.

How does Vemlidy work?

The active substance in Vemlidy, tenofovir alafenamide, works by stopping the hepatitis B virus in the liver from multiplying. It is converted in the body into its active compound tenofovir, which blocks the activity of reverse transcriptase, an enzyme made by the hepatitis B virus that allows it to reproduce itself in the cells it has infected.

What benefits of Vemlidy have been shown in studies?

Vemlidy reduces levels of hepatitis B virus in most patients. In a study of 426 patients with ‘e-antigen negative’ chronic hepatitis, 94% of patients on Vemlidy had very low levels of viral DNA after 48 weeks of treatment. This result was similar to that in patients taking another form of tenofovir (tenofovir disoproxil fumarate) where 93% had very low viral DNA levels.

In a second study of 875 patients with ‘e-antigen positive’ chronic hepatitis, 64% of patients taking Vemlidy and 67% of those taking tenofovir disoproxil fumarate had very low levels of viral DNA after 48 weeks. These

results suggest that the comparator medicine might be more effective in 'e-antigen positive' cases but differences seen are small.

The terms 'e-antigen positive' and 'e-antigen negative' refer to the presence or absence of e-antigen, a hepatitis B viral protein. If this protein is present, it means that the virus is multiplying rapidly and the viral load may be higher.

What are the risks associated with Vemlidy?

The most common side effects with Vemlidy are headache (11% of patients), nausea (6% of patients) and tiredness (6% of patients). For the full list of side effects and restrictions see the package leaflet.

Why is Vemlidy approved?

Vemlidy suppresses levels of hepatitis B virus in the body, and its effectiveness is comparable to that of another tenofovir medicine (tenofovir disoproxil fumarate). With regard to its risks, the side effects of Vemlidy are manageable. In addition, Vemlidy is effective at a lower dose than tenofovir disoproxil fumarate and may lead to reduced side effects in the kidneys and bones.

The Agency's Committee for Medicinal Products for Human Use (CHMP) therefore concluded that the benefits of Vemlidy outweigh its risks and recommended its approval in the EU.

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

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

Other information about Vemlidy

The European Commission granted a marketing authorisation valid throughout the European Union for Vemlidy on 9 January 2017.

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

Vemlidy : EPAR - Summary for the public (PDF/78.83 KB)

First published: 10/03/2017
Last updated: 10/03/2017
EMA/788418/2016

Available languages (22)

Vemlidy : EPAR - Risk-management-plan summary (PDF/104.66 KB) (new)

First published: 18/08/2021

More detail is available in the summary of product characteristics

This EPAR was last updated on 18/08/2021

Authorisation details

Product details	
Name	Vemlidy
Agency product number	EMEA/H/C/004169
Active substance	tenofovir alafenamide fumarate
International non-proprietary name (INN) or common name	tenofovir alafenamide

Product details

Therapeutic area (MeSH)	Hepatitis B
Anatomical therapeutic chemical (ATC) code	J05AF
Additional monitoring ▼	This medicine is under additional monitoring, meaning that it is monitored even more intensively than other medicines. For more information, see Medicines under additional monitoring.

Publication details

Marketing-authorisation holder	Gilead Sciences Ireland UC
Revision	11
Date of issue of marketing authorisation valid throughout the European Union	09/01/2017
Contact address	IDA Business & Technology Park Carrigtohill County Cork T45 DP77 Ireland

Product information

08/07/2021 Vemlidy - EMEA/H/C/004169 - II/0030

Vemlidy : EPAR - Product Information (PDF/543.59 KB) (updated)

First published: 10/03/2017
Last updated: 18/08/2021

Available languages (24)

Contents

- Annex I - Summary of product characteristics
- Annex IIA - Manufacturing-authorisation holder responsible for batch release
- Annex IIB - Conditions of the marketing authorisation
- Annex IIIA - Labelling
- Annex IIIB - Package leaflet

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.

Vemlidy : EPAR - All Authorised presentations (PDF/47.91 KB)

First published: 10/03/2017
Last updated: 10/03/2017

Available languages (24)

Pharmacotherapeutic group

Antivirals for systemic use

Therapeutic indication

Vemlidy is indicated for the treatment of chronic hepatitis B in adults and adolescents (aged 12 years and older with body weight at least 35 kg).

Assessment history

Changes since initial authorisation of medicine

Vemlidy : EPAR - Procedural steps taken and scientific information after authorisation (PDF/198.04 KB) (updated)

First published: 19/12/2017
Last updated: 18/08/2021

Vemlidy-H-C-PSUSA-00010575-201911 : EPAR - Scientific conclusions and grounds for the variation to the terms of the marketing authorisation((PDF/100.83 KB)

First published: 14/09/2020
EMA/322640/2020

Initial marketing-authorisation documents

Vemlidy : EPAR - Public assessment report (PDF/5.04 MB)

Adopted

First published: 10/03/2017
Last updated: 10/03/2017
EMA/793580/2016

CHMP summary of positive opinion for Vemlidy (PDF/73.79 KB)

Adopted

First published: 11/11/2016
Last updated: 11/11/2016
EMA/704543/2016

News

- Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 7-10 November 2016

  11/11/2016

- Clinical data (initial marketing authorisation)

Related content

- Vemlidy: Paediatric investigation plan

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