EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Vemlidy

*tenofovir alafenamide*

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 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)

First published: 18/08/2021

This EPAR was last updated on 05/09/2022

## Authorisation details

| Product details | |
|---|---|
| Name | Vemlidy |
| Agency product number | EMEA/H/C/004169 |
| Active substance | tenofovir alafenamide fumarate |

| Product details | |
|---|---|
| International non-proprietary name (INN) or common name | tenofovir alafenamide |
| Therapeutic area (MeSH) | Hepatitis B |
| Anatomical therapeutic chemical (ATC) code | J05AF |

| Publication details | |
|---|---|
| Marketing-authorisation holder | Gilead Sciences Ireland UC |
| Revision | 14 |
| Date of issue of marketing authorisation valid throughout the European Union | 09/01/2017 |
| Contact address | IDA Business & Technology Park<br>Carrigtohill<br>County Cork<br>T45 DP77<br>Ireland |

## Product information

17/08/2022 Vemlidy - EMEA/H/C/004169 - PSUSA/00010575/202111

Vemlidy : EPAR - Product Information (PDF/493 KB) (updated)

First published: 10/03/2017
Last updated: 05/09/2022

Available languages (25)

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.*

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/232.35 KB) (updated)

First published: 19/12/2017
Last updated: 05/09/2022

Vemlidy-H-C-PSUSA-00010575-202111 : EPAR - Scientific conclusions and grounds for the variation to the terms of the marketing authorisation (PDF/139.35 KB) (new)

First published: 05/09/2022
EMA/725885/2022

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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