EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

← Medicines

Vemlidy

tenofovir alafenamide

Medicine Human

Authorised

This medicine is authorised for use in the European Union

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Page contents

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.

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

Other information about Vemlidy

Vemlidy : EPAR - Summary for the public
Reference Number: EMA/788418/2016

English (EN) (78.83 KB - PDF)
First published: 10/03/2017
Last updated: 10/03/2017

View

Other languages (22)

Vemlidy : EPAR - Risk management plan

English (EN) (1.6 MB - PDF)
First published: 18/08/2021
Last updated: 17/09/2024

View

Product information

Vemlidy : EPAR - Product Information

English (EN) (595.53 KB - PDF)
First published: 10/03/2017
Last updated: 31/05/2023

View

Other languages (24)

Latest procedure affecting product information:
II/0040

26/05/2023

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).

Vemlidy : EPAR - All Authorised presentations

English (EN) (47.91 KB - PDF)
First published: 10/03/2017
Last updated: 10/03/2017

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Other languages (24)

Product details

Name of medicine
Vemlidy

Active substance
tenofovir alafenamide fumarate

International non-proprietary name (INN) or common name
tenofovir alafenamide

Therapeutic area (MeSH)
Hepatitis B

Anatomical therapeutic chemical (ATC) code
J05AF13

Pharmacotherapeutic group

Antivirals for systemic use

Therapeutic indication

Vemlidy is indicated for the treatment of chronic hepatitis B (CHB) in adults and paediatric patients 6 years of age and older weighing at least 25 kg (see section 5.1).

Authorisation details

EMA product number
EMEA/H/C/004169

Marketing authorisation holder
Gilead Sciences Ireland UC
IDA Business & Technology Park
Carrigtohill
County Cork
T45 DP77
Ireland

Opinion adopted
10/11/2016

Marketing authorisation issued
09/01/2017

Revision

17

Assessment history

Changes since initial authorisation of medicine

Initial marketing authorisation documents

News on Vemlidy

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 24 - 26 April 2023

26/04/2023

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

11/11/2016

- Clinical data (initial marketing authorisation)

More information on Vemlidy

- EMEA-001584-PIP01-13-M07 - paediatric investigation plan

Topics

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