



← Medicines

Maviret

glecaprevir / pibrentasvir

Medicine

Human

✓ **Authorised**

This medicine is authorised for use in the European Union

Share

RSS

- Application under evaluation
- CHMP opinion
- **European Commission decision**

Overview

Maviret is an antiviral medicine used to treat adults and children from 3 years of age with chronic (long-term) hepatitis C, an infectious disease that affects the liver, which is caused by the hepatitis C virus.

Maviret contains the active substances glecaprevir and pibrentasvir.

How is Maviret used?



How does Maviret work?	∨
What benefits of Maviret have been shown in studies?	∨
What are the risks associated with Maviret?	∨
Why is Maviret authorised in the EU?	∨
What measures are being taken to ensure the safe and effective use of Maviret?	∨
Other information about Maviret	∨



Maviret : EPAR - Medicine overview

Reference Number: EMA/409726/2017

English (EN) (117.41 KB - PDF)

First published: 17/08/2017

Last updated: 28/07/2021

[View](#)

[Other languages \(22\)](#) ∨



Maviret : EPAR - Risk-management-plan summary

English (EN) (39.96 KB - PDF)

First published: 24/04/2019

Last updated: 16/02/2023

[View](#) 

Product information



Maviret : EPAR - Product information

English (EN) (587.83 KB - PDF)

First published: 17/08/2017

Last updated: 02/03/2023

[View](#) [Other languages \(24\)](#) ▼

Latest procedure affecting product information:

IB/0055

02/03/2023



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).



Maviret : EPAR - All Authorised presentations

English (EN) (30.82 KB - PDF)

First published: 17/08/2017

Last updated: 01/09/2021

[View](#) 

[Other languages \(24\)](#) ▼

Product details

Name of medicine

Maviret

Active substance

- glecaprevir
- pibrentasvir

International non-proprietary name (INN) or common name

- glecaprevir
- pibrentasvir

Therapeutic area (MeSH)

Hepatitis C, Chronic

Anatomical therapeutic chemical (ATC) code

J05AP57

Pharmacotherapeutic group

Antivirals for systemic use

Therapeutic indication

Maviret is indicated for the treatment of chronic hepatitis C virus (HCV) infection in adults and children aged 3 years and older.

Maviret coated granules is indicated for the treatment of chronic hepatitis C virus (HCV) infection in children 3 years and older.

Authorisation details

EMA product number

EMA/H/C/004430

A Accelerated assessment

This medicine had an accelerated assessment. This means that it is a medicine of major interest for public health, so its timeframe for review was 150 evaluation days rather than 210. For more information, see [Accelerated assessment](#).

Marketing authorisation holder

AbbVie Deutschland GmbH Co. KG
Knollstrasse
67061 Ludwigshafen
Germany

Opinion adopted

22/06/2017

Marketing authorisation issued

26/07/2017

Revision

22

Assessment history

Changes since initial authorisation of medicine



Initial marketing authorisation documents



News on Maviret

[Meeting highlights from the Committee for Medicinal Products for Human Use \(CHMP\) 19-22 April 2021](#)

23/04/2021

[Meeting highlights from the Committee for Medicinal Products for Human Use \(CHMP\) 28-31 January 2019](#)

01/02/2019

[Meeting highlights from the Committee for Medicinal Products for Human Use \(CHMP\) 19-22 June 2017](#)

23/06/2017

[Two new medicines recommended for the treatment of chronic hepatitis C](#)

23/06/2017

More information on Maviret

- [EMEA-001832-PIP01-15-M02 - paediatric investigation plan](#)

Topics

[Medicines](#)

This page was last updated on 09/06/2023

Share this page



E-mail



LinkedIn



X



Facebook



More share options



**Product emergency hotline
OUTSIDE WORKING HOURS**

[About us](#)

[What we do](#)

[Careers](#)

[Committees & working parties](#)

[Regulatory network](#)

[European experts](#)

[Languages](#)

[Frequently asked questions](#)

[Glossaries](#)

[About this website](#)

[Privacy](#)

[Cookies](#)

[Search tips](#)

[Access to documents](#)

[Contacts](#)

[Send a question](#)

[EMA Service Desk \(system support\)](#)

[Services and databases](#)

[European Medicines Agency](#)

[Domenico Scarlattilaan 6](#)

[1083 HS Amsterdam](#)

[The Netherlands](#)

[Tel: +31 \(0\)88 781 6000](#)

[How to find us](#)

[Postal address and deliveries](#)

[Business hours and holidays](#)



[RSS Feed](#)



[X](#)



[YouTube](#)



[LinkedIn](#)

© 1995 - 2024 European Medicines Agency

European Union agencies network



