Adopted

First published: 05/02/2014
Last updated: 05/02/2014
EMA/CHMP/688774/2013

- List item

CHMP summary of positive opinion for Sovaldi (PDF/63.99 KB)

Adopted

First published: 22/11/2013
Last updated: 22/11/2013
EMA/CHMP/687741/2013

News

- Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 17-20 July 2017

  21/07/2017

- Direct-acting antivirals for hepatitis C: EMA confirms recommendation to screen for hepatitis B

  16/12/2016

- PRAC warns of risk of hepatitis B re-activation with direct-acting antivirals for hepatitis C

  02/12/2016

- Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 20-23 April 2015

  24/04/2015

- EMA recommends avoidance of certain hepatitis C medicines and amiodarone together

  24/04/2015

- World Hepatitis Day – European Medicines Agency uses regulatory tools to facilitate patient access to innovative medicines

25/07/2014

- European Medicines Agency recommends approval of Daklinza in chronic hepatitis C

27/06/2014

- European Medicines Agency advises on compassionate use of a new combination therapy for chronic hepatitis C

21/02/2014

- Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 18-21 November 2013

22/11/2013

- European Medicines Agency recommends approval of sofosbuvir for the treatment of chronic hepatitis C

22/11/2013

Related content

- Direct-acting antivirals indicated for treatment of hepatitis C (interferon-free): Article 20 procedures
- Sovaldi: Paediatric investigation plan

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DR. POWELL

Sovaldi

sofosbuvir

Table of contents

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

Overview

Sovaldi is an antiviral medicine used in combination with other medicines to treat adults and children from 12 years of age with chronic (long-term) hepatitis C, an infection caused by the hepatitis C virus that affects the liver.

Sovaldi contains the active substance sofosbuvir.

List item

Sovaldi : EPAR - Medicine overview (PDF/86.98 KB)

First published: 05/02/2014
Last updated: 18/02/2019
EMA/570417/2018

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List item

Sovaldi : EPAR - Risk-management-plan summary (PDF/55.04 KB)

First published: 18/02/2019
Last updated: 06/11/2019

More detail is available in the summary of product characteristics

This EPAR was last updated on 06/11/2019

Authorisation details

	Product details
Name	Sovaldi
Agency product number	EMEA/H/C/002798
Active substance	Sofosbuvir
International non-proprietary name (INN) or common name	sofosbuvir
Therapeutic area (MeSH)	Hepatitis C, Chronic
Anatomical therapeutic chemical (ATC) code	J05AX15
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.
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.

First published: 30/08/2019
EMA/447250/2019

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Sovaldi-H-C-PSUSA-00010134-201712 : EPAR - Scientific conclusions and grounds for the variation to the terms of the marketing authorisation (PDF/69.46 KB)

First published: 16/10/2018
EMA/714062/2018

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Sovaldi-H-C-2798-II-0036 : EPAR - Assessment Report - Variation (PDF/1.27 MB)

Adopted

First published: 18/10/2017
Last updated: 18/10/2017
EMA/508676/2017

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CHMP post-authorisation summary of positive opinion for Sovaldi (PDF/66.95 KB)

First published: 21/07/2017
Last updated: 21/07/2017
EMA/CHMP/428252/2017

- List item

Sovaldi-H-C-2798-A20-0029 : EPAR - Scientific Conclusion (PDF/58.19 KB)

First published: 13/03/2017
Last updated: 13/03/2017

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List item

Sovaldi-H-C-2798-A20-0029 : EPAR - Assessment Report - Variation (PDF/339.32 KB)

Adopted

First published: 13/03/2017
Last updated: 13/03/2017
EMA/103226/2017

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Sovaldi-H-C-PSUSA-00010134-201512 : EPAR - Scientific conclusions and grounds for the variation to the terms of the marketing authorisation (PDF/67.47 KB)

First published: 23/09/2016
Last updated: 23/09/2016
EMA/630308/2016

Initial marketing-authorisation documents

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Sovaldi : EPAR - Public assessment report (PDF/1.67 MB)

Publication details

Marketing-authorisation holder	Gilead Sciences Ireland UC
Revision	19
Date of issue of marketing authorisation valid throughout the European Union	16/01/2014
Contact address	IDA Business & Technology Park Carrigtohill County Cork T45 DP77 Ireland

Product information

21/10/2019 Sovaldi - EMEA/H/C/002798 - WS/1518

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  Sovaldi : EPAR - Product Information (PDF/623.71 KB)

  First published: 05/02/2014
  Last updated: 06/11/2019

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Sovaldi : EPAR - All Authorised presentations (PDF/15.13 KB)

First published: 05/02/2014
Last updated: 05/02/2014

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Pharmacotherapeutic group

Antivirals for systemic use

Therapeutic indication

Sovaldi is indicated in combination with other medicinal products for the treatment of chronic hepatitis C (CHC) in adults and in adolescents aged 12 to 18 years (see sections 4.2, 4.4 and 5.1).

For hepatitis C virus (HCV) genotype specific activity, see sections 4.4 and 5.1.

Assessment history

Changes since initial authorisation of medicine

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List item

Sovaldi : EPAR - Procedural steps taken and scientific information after authorisation (PDF/237.58 KB)

First published: 26/08/2014
Last updated: 06/11/2019

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Sovaldi-H-C-PSUSA-00010134-201812 : EPAR - Scientific conclusions and grounds for the variation to the terms of the marketing authorisation (PDF/70.6 KB)

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