



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Sovaldi

sofosbuvir

On 21 November 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Sovaldi, 400 mg, film-coated tablet intended for the treatment of chronic hepatitis C (CHC). The applicant for this medicinal product is Gilead Sciences International Ltd. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Sovaldi is sofosbuvir, a direct acting antiviral (ATC code not yet assigned). The active metabolite of sofosbuvir is a pangenotypic inhibitor of the hepatitis C virus (HCV) NS5B RNA polymerase.

The benefits of Sovaldi used in combination with other medicinal products is its ability to inhibit viral replication in infected host cells which can lead to the eradication of the virus, correlating to a cure of chronic hepatitis C virus infection. Sovaldi provides the first interferon-free treatment option for chronic hepatitis C. In patients where interferon is still needed for efficacy, Sovaldi enables a shortened treatment duration compared to current standard-of-care. Furthermore, when used before liver transplantation, Sovaldi can prevent graft reinfection with HCV.

The most common side effects when Sovaldi is used in combination with ribavirin, or in combination with ribavirin and peginterferon alfa, were fatigue, headache, nausea and insomnia. The safety profile of Sovaldi in combination with ribavirin +/- peginterferon alfa was consistent with the expected safety profile of ribavirin and peginterferon alfa treatment, without increasing the frequency or severity of the expected adverse drug reactions.

A pharmacovigilance plan for Sovaldi will be implemented as part of the marketing authorisation.

The approved indication is: "Sovaldi is indicated in combination with other medicinal products for the treatment of chronic hepatitis C (CHC) in adults (see sections 4.2, 4.4 and 5.1). For hepatitis C virus (HCV) genotype specific activity, see sections 4.4 and 5.1".

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.



It is proposed that treatment with Sovaldi should be initiated and monitored by a physician experienced in the management of CHC.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Sovaldi and therefore recommends the granting of the marketing authorisation.