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Sovaldi (*sofosbuvir*)

An overview of Sovaldi and why it is authorised in the EU

What is Sovaldi and what is it used for?

Sovaldi is an antiviral medicine used in combination with other medicines to treat adults and children from 3 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.

How is Sovaldi used?

Sovaldi can only be obtained with a prescription and treatment should be started and monitored by a doctor experienced in the management of patients with chronic hepatitis C.

Sovaldi is available as tablets and granules in a sachet. The granules are suitable for children and patients who cannot take tablets and they can be sprinkled on soft food, swallowed with water or swallowed dry without chewing.

For adults, the recommended dose of Sovaldi is 400 mg sofosbuvir once a day. For children and young people aged up to 18 years, the daily dose depends on their weight. Sovaldi is normally taken for 12 or 24 weeks.

Sovaldi must be used in combination with other medicines used to treat chronic hepatitis C, such as ribavirin or peginterferon alfa (a form of the natural substance, interferon) and ribavirin. Sovaldi can be used in all 6 varieties (genotypes) of hepatitis C virus. For children, Sovaldi is recommended for genotypes 2 or 3. The duration of treatment will depend on the genotype of the virus the patient is infected with and on which medicines are used with Sovaldi.

For further information about using Sovaldi, see the package leaflet or contact your doctor or pharmacist.

How does Sovaldi work?

The active substance in Sovaldi, sofosbuvir, blocks the action of a protein called NS5B RNA-dependent RNA polymerase in the hepatitis C virus, which is essential for the virus to multiply. This stops the hepatitis C virus from multiplying and infecting new cells.

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What benefits of Sovaldi have been shown in studies?

Sovaldi has been investigated in four main studies involving a total of 1,305 adult patients infected with hepatitis C. In all four studies, the main measure of effectiveness was the number of patients whose blood tests did not show any sign of hepatitis C virus 12 weeks after the end of treatment.

- The first study involved 327 previously untreated patients who were infected with hepatitis C virus of genotypes 1, 4, 5 or 6, and who were given Sovaldi together with two other antiviral medicines, peginterferon alfa and ribavirin, for 12 weeks. In this study, 91% (296 out of 327) of patients had no sign of the virus 12 weeks after the end of treatment.
- The second study involved 499 previously untreated patients who had hepatitis C of genotypes 2 or 3. In this study, patients given Sovaldi together with ribavirin for 12 weeks were compared with patients given peginterferon alfa and ribavirin for 24 weeks. Treatment with Sovaldi was as effective (67% patients – 171 out of 256 – had no sign of the virus) as peginterferon-based treatment (67% of patients – 162 out of 243).
- The third study involved 278 patients with genotypes 2 or 3 hepatitis C virus who could not take or did not want to have treatment with interferon. This study investigated 12 weeks of treatment with Sovaldi and ribavirin compared with placebo (a dummy treatment) and found that 78% (161 out of 207) of patients taking Sovaldi and ribavirin had no sign of the hepatitis C virus 12 weeks after treatment, whereas none of 71 patients taking placebo were free of the virus.
- The fourth study involved 201 patients with hepatitis C virus (genotypes 2 or 3) whose infection did not improve on previous treatment with interferon or whose infections came back. This study compared Sovaldi and ribavirin taken for 12 weeks with Sovaldi and ribavirin taken for 16 weeks. In this study, 50% (51 out of 103) of patients taking Sovaldi and ribavirin for 12 weeks had no sign of the hepatitis C virus, compared with 71% (70 out of 98) of patients treated for 16 weeks.
- A fifth study involved 106 children and adolescents aged 3 to 17 years with hepatitis C virus (genotypes 2 or 3) who were treated with Sovaldi and ribavirin for 12 or 24 weeks. Around 98% of patients (51 out of 52) aged 12 to 17 years and 100% (41 out of 41) children aged from 6 to 11 years had no sign of the hepatitis C virus after treatment. In children aged 3 to 6 years, 4 out of 5 infected with the genotype 2 virus were cleared of the virus and all 8 infected with the genotype 3 virus were cleared of the virus.

Additional studies showed that Sovaldi in combination with ribavirin decreased the risk of infection of the new liver with hepatitis C virus in adult patients undergoing transplantation, that Sovaldi is also effective in patients infected with both hepatitis C and HIV, and that the outcome of patients with genotype 3 infection could be improved by extending treatment to 24 weeks.

What are the risks associated with Sovaldi?

The most common side effects with Sovaldi in combination with ribavirin and peginterferon alfa were similar to those commonly reported with ribavirin or peginterferon alfa and included tiredness, headache, nausea (feeling sick) and insomnia (difficulty sleeping). For the full list of side effects of Sovaldi, see the package leaflet.

Sovaldi must not be used together with certain types of medicines which can reduce the effects of Sovaldi. Such medicines include:

- rifampicin (an antibiotic for serious infections like tuberculosis);
- St. John’s wort (a herbal preparation used to treat depression and anxiety);

- carbamazepine, phenobarbital and phenytoin (medicines for epilepsy).

For the full list of restrictions, see the package leaflet.

Why is Sovaldi authorised in the EU?

The European Medicines Agency decided that Sovaldi's benefits are greater than its risks and it can be authorised for use in the EU. Sovaldi allows the virus to be cleared without the patient having to take peginterferon alfa or with only short courses of this medicine (which can cause serious side effects, including reduced growth in adolescents).

The Agency also considered that giving Sovaldi in combination with ribavirin before a liver transplant can prevent re-infection of the liver, which in the absence of treatment occurs nearly always and results in a poor prognosis. In addition, virus resistance to Sovaldi is rare and Sovaldi works against all types of hepatitis C virus.

Regarding safety, the Agency noted that, although there is limited information in some groups of patients such as those with decompensated liver disease (where the liver is damaged and no longer works properly), no side effects specific to Sovaldi have been identified, and those that occur are mainly due to combined treatment with ribavirin or interferons.

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

The company that markets Sovaldi will carry out a study in patients who have had liver cancer to evaluate the risk of the cancer returning after treatment with direct-acting antivirals such as Sovaldi. The study is being carried out because of data suggesting that patients treated with these medicines who have had liver cancer could be at risk of their cancer returning early.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Sovaldi have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Sovaldi are continuously monitored. Side effects reported with Sovaldi are carefully evaluated and any necessary action taken to protect patients.

Other information about Sovaldi

Sovaldi received a marketing authorisation valid throughout the EU on 16 January 2014.

Further information on Sovaldi can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/sovaldi.

This overview was last updated in 05-2020.