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EPAR summary for the public

Exviera

dasabuvir

This is a summary of the European public assessment report (EPAR) for Exviera. 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 Exviera.

For practical information about using Exviera, patients should read the package leaflet or contact their doctor or pharmacist.

What is Exviera and what is it used for?

Exviera is an antiviral medicine used in combination with other medicines to treat adults with chronic (long-term) hepatitis C, an infectious disease of the liver caused by the hepatitis C virus.

It contains the active substance dasabuvir.

How is Exviera used?

Exviera can only be obtained with a prescription and treatment should be started and monitored by a doctor experienced in managing patients with chronic hepatitis C.

Exviera is available as 250 mg tablets, and the recommended dose is two tablets a day, one in the morning and one in the evening for 8, 12 or 24 weeks.

Exviera is always used in combination with another medicine, Viekirax, which contains the active substances ombitasvir, paritaprevir and ritonavir. Some patients taking Exviera are also treated with another antiviral medicine, ribavirin, in addition to Viekirax.

Several varieties (genotypes) of hepatitis C virus exist and Exviera is recommended for use in patients with virus of genotypes 1a and 1b. The combination of medicines used and the duration of treatment will depend on which genotype of hepatitis C virus the patient is infected with, the nature of the liver

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problems they have (for example, if they have liver cirrhosis (scarring) or their liver is not working properly) and whether they have received previous treatment. For further information, see the package leaflet.

How does Exviera work?

The active substance in Exviera, dasabuvir, works by blocking the action of an enzyme in the hepatitis C virus called 'NS5B RNA-dependent polymerase', which the virus needs to multiply. This stops the hepatitis C virus from multiplying and infecting new cells.

What benefits of Exviera have been shown in studies?

In 6 initial main studies involving around 2,300 patients infected with hepatitis C virus genotypes 1a or 1b, Exviera in combination with Viekirax was effective in clearing the virus from the blood. Between 96% and 100% of patients without liver scarring had their blood cleared of the virus after 12 weeks of treatment (with or without ribavirin).

In patients with liver scarring, Exviera treatment in combination with Viekirax and ribavirin resulted in a clearance rate of between 93% and 100% after 24 weeks of treatment. In a seventh study, patients with liver scarring but stable liver function (compensated cirrhosis) who had genotype 1b infection were treated with Exviera and Viekirax without ribavirin and 100% of patients (60 out of 60 patients) had their blood cleared of the virus.

What are the risks associated with Exviera?

The most common side effects with Exviera when used with Viekirax and ribavirin (which may affect more than 1 in 10 people) are insomnia (difficulty sleeping), nausea, pruritus (itching), asthenia (weakness) and fatigue (tiredness). For the full list of all side effects, see the package leaflet.

Exviera must not be used in women taking ethinylestradiol, an oestrogen found in hormonal contraceptives. It must also not be used together with medicines that affect the activity of certain enzymes that can raise or lower the level of the active substance in the blood. For the full list of restrictions, see the package leaflet.

Why is Exviera approved?

The European Medicines Agency noted that Exviera used in combination with Viekirax is effective in clearing the hepatitis C virus genotypes 1a and 1b from the blood with and without ribavirin. Almost all the patients in the studies had the virus cleared from their blood after 12 or 24 weeks. The clearance rate was particularly high in patients infected with genotype 1b.

Regarding its safety, although there were some cases of raised liver enzymes in patients treated with Exviera in combination with Viekirax and ribavirin, side effects seen with this combination were generally well tolerated. The Agency therefore concluded that the benefits of Exviera outweigh its risks and recommended that it be approved for use in the EU.

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

The company that markets Exviera will carry out a study in patients who previously have had liver cancer to evaluate the risk of liver cancer returning after treatment with direct-acting antivirals such as

Exviera. This study is being carried out in light 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 Exviera have also been included in the summary of product characteristics and the package leaflet.

Other information about Exviera

The European Commission granted a marketing authorisation valid throughout the European Union for Exviera on 15 January 2015.

The full EPAR and risk management plan summary for Exviera can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Exviera, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2017.