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Viekirax (*ombitasvir / paritaprevir / ritonavir*)

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

What is Viekirax and what is it used for?

Viekirax 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 3 active substances: ombitasvir, paritaprevir and ritonavir.

How is Viekirax used?

Viekirax 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.

Viekirax is available as tablets containing 12.5 mg ombitasvir, 75 mg paritaprevir and 50 mg ritonavir. The recommended dose is two tablets taken once a day with food for 8, 12 or 24 weeks. Viekirax is always used in combination with other medicines for chronic hepatitis C, such as dasabuvir and ribavirin.

Several varieties (genotypes) of hepatitis C virus exist, and Viekirax is recommended for patients with virus of genotypes 1a, 1b and 4. The combination of medicines used and the duration of treatment will depend on the genotype of hepatitis C virus infecting the patient, the nature of the patient's liver problems, for example if they have liver cirrhosis (scarring) or their liver is not working properly, and whether they have received previous treatment.

For more information about using Viekirax, see the package leaflet or contact your doctor or pharmacist.

How does Viekirax work?

The 3 active substances in Viekirax work in different ways: ombitasvir blocks the action of a protein in the hepatitis C virus called 'NS5A' and paritaprevir blocks the action of another protein called 'NS3/4A', both of which the virus needs to multiply. By blocking these proteins, the medicine prevents the hepatitis C virus from multiplying and infecting new cells.

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The third active substance, ritonavir, does not act directly against hepatitis C virus but it blocks the action of an enzyme called CYP3A that breaks down paritaprevir. This slows the removal of paritaprevir from the body, allowing paritaprevir to act against the virus for longer.

What benefits of Viekirax have been shown in studies?

In 6 initial main studies involving around 2,300 patients infected with hepatitis C virus genotypes 1a or 1b, Viekirax in combination with dasabuvir 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 ribivarin). In patients with liver scarring, Viekirax treatment in combination with dasabuvir 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.

An additional study showed Viekirax to be effective against genotype 4: when given with ribavirin, Viekirax cleared this genotype from the blood of all the 91 patients infected with it after 12 weeks. When Viekirax was given with dasabuvir, the virus was cleared from the blood in 91% of the patients.

What are the risks associated with Viekirax?

The most common side effects with Viekirax in combination with dasabuvir and ribavirin (which may affect more than 1 in 5 people) are tiredness and nausea (feeling sick).

Viekirax must not be used in patients with moderate to severe liver impairment and in women taking ethinylestradiol, an oestrogen found in hormonal contraceptives. It must also not be used together with medicines that can raise or lower the levels of Viekirax's active substances in the blood.

For the full list of side effects and restrictions of Viekirax, see the package leaflet.

Why is Viekirax authorised in the EU?

The European Medicines Agency noted that Viekirax in combination with other medicines is effective in clearing the hepatitis C virus genotypes 1a, 1b and 4, including in patients with liver scarring. Almost all the patients with these genotypes treated in studies had the virus cleared from their blood. The clearance rate was particularly high in patients infected with genotypes 1b and 4.

Although there were some cases of raised liver enzymes in patients treated with Viekirax in combination with dasabuvir and ribavirin, side effects with this combination were generally well tolerated. The Agency therefore decided that Viekirax's benefits are greater than its risks and it can be authorised for use in the EU.

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

The company that markets Viekirax will carry out a study in patients who have had liver cancer to evaluate the risk of liver cancer returning after treatment with direct-acting antivirals such as Viekirax. 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 Viekirax have also been included in the summary of product characteristics and the package leaflet.

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

Other information about Viekirax

Viekirax received a marketing authorisation valid throughout the EU on 15 January 2015.

Further information on Viekirax can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

This overview was last updated in 08-2018.