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EPAR summary for the public

Daklinza

daclatasvir

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

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

What is Daklinza and what is it used for?

Daklinza 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 daclatasvir.

How is Daklinza used?

Daklinza 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.

Daklinza is available as 30, 60, and 90 mg tablets. The usual dose is 60 mg once a day for 12 or 24 weeks. The dose may have to be raised or lowered if the patient is taking other medicines that decrease or increase Daklinza's effects. Daklinza must be used in combination with other medicines for chronic hepatitis C, such as sofosbuvir, peginterferon alfa and ribavirin.

Several varieties (genotypes) of hepatitis C virus exist and Daklinza is recommended for use in patients with virus of genotypes 1, 3 and 4. The combination of medicines to use and the duration of treatment will depend on the genotype of hepatitis C virus the patient is infected with and the nature of the liver problem, for example liver cirrhosis (scarring) or the liver not working well enough. For further information, see the package leaflet.

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How does Daklinza work?

The active substance in Daklinza, daclatasvir, blocks the action of a protein in the hepatitis C virus called 'NS5A', which is essential for the virus to multiply. By blocking this protein, the medicine stops the hepatitis C virus from multiplying.

What benefits of Daklinza have been shown in studies?

Daklinza used in combination with sofosbuvir (with or without ribavirin) was effective at clearing the hepatitis C virus from the blood in a main study involving 211 adults. The patients in the study were infected with genotypes 1, 2 or 3 and all received treatment for 12 or 24 weeks. Most patients had not previously been treated for hepatitis C, though some had genotype 1 infection that was resistant to standard medicines (consisting of either telaprevir or boceprevir – the so-called NS3/4A inhibitors - in combination with peginterferon alfa and ribavirin).

Around 99% of patients with genotype 1 infection (125 out of 126), 96% of patients with genotype 2 infection (25 out of 26) and 89% of patients with genotype 3 infection (16 out of 18) did not show any sign of the virus in their blood 12 weeks after the end of their planned treatment.

Additional studies involving patients with genotypes 4 indicate that Daklinza is also as effective against genotype 4 as it is against genotype 1.

What are the risks associated with Daklinza?

The most common side effects reported with Daklinza in combination with sofosbuvir with or without ribavirin are fatigue (tiredness), nausea (feeling sick) and headache. For the full list of all side effects reported with Daklinza, see the package leaflet.

Daklinza must not be used together with certain medicines that may reduce the effects of Daklinza. For more information on the medicines that should not be taken with Daklinza, see the package leaflet.

Why is Daklinza approved?

The European Medicines Agency noted that Daklinza used in combination with other medicines was shown to be effective against hepatitis C virus, including in patients with genotype 1 resistant to previous treatment. Almost all the patients in the main study had the virus cleared from their blood.

Regarding its safety, Daklinza was well tolerated and the side effects were similar to those experienced by patients taking placebo.

The Agency therefore concluded that the benefits of Daklinza 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 Daklinza?

The company that markets Daklinza 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 Daklinza. 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 Daklinza have also been included in the summary of product characteristics and the package leaflet.

Other information about Daklinza

The European Commission granted a marketing authorisation valid throughout the European Union for Daklinza on 22 August 2014.

The full EPAR and risk management plan summary for Daklinza 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 Daklinza, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2017.