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Alpivab (*peramivir*)

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

What is Alpivab and what is it used for?

Alpivab is an antiviral medicine that contains the active substance peramivir. It is used to treat uncomplicated influenza (flu) in adults and children over 2 years. Uncomplicated means that the flu has typical features (such as fever, aches, cough, sore throat and runny nose) and is not made worse by other conditions.

How is Alpivab used?

Alpivab is available as a solution to be diluted for infusion (drip) into a vein. The medicine can only be obtained with a prescription. Alpivab is given as an infusion lasting 15 to 30 minutes. The dose depends on age and body weight and should be reduced in adults and adolescents over 13 years of age with reduced kidney function. It is given once only, within 48 hours after symptoms start.

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

How does Alpivab work?

The active substance in Alpivab, peramivir, prevents the flu virus from spreading further by blocking the activity of enzymes (proteins) on the surface of the virus called neuraminidases. Peramivir works on neuraminidases of both influenza-A (the most common type) and influenza-B viruses.

What benefits of Alpivab have been shown in studies?

Alpivab was shown to reduce the length of time symptoms lasted in patients with influenza.

Alpivab was compared with placebo (a dummy treatment) in one main study of 296 adults with influenza (mostly influenza A) treated within 48 hours of symptoms appearing. The main measure of effectiveness was the length of time before symptoms (cough, sore throat, headache, blocked nose, feverishness or chills, aches or pains of the muscle or joints and tiredness) got better. Symptoms took around 2 and a half days (59 hours) to get better in patients taking Alpivab in comparison with just under 3 and a half days (82 hours) in patients taking placebo.

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What are the risks associated with Alpivab?

The most common side effects with Alpivab (which may affect up to around 3 in 100 people) are a decrease in the levels of neutrophils (a type of white blood cell) and nausea (feeling sick). Serious side effects with Alpivab are anaphylaxis (a severe allergic reaction) and skin reactions, including erythema multiforme (an allergic skin reaction) and Stevens-Johnson Syndrome (life-threatening reaction with flu-like symptoms and painful rash affecting the skin, mouth, eyes and genitals).

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

Why is Alpivab authorised in the EU?

Alpivab reduces the length of time flu symptoms last by one day on average. Although this difference is not large, it may benefit some patients. There is a risk of severe allergic reactions, and although it is not known exactly how often these reactions occur, they appear to be rare. The European Medicines Agency decided that Alpivab'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 Alpivab?

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

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

Other information about Alpivab

Alpivab received a marketing authorisation valid throughout the EU on 13 April 2018.

Further information on Alpivab 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 04-2018.