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Dectova (*zanamivir*)

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

What is Dectova and what is it used for?

Dectova is an antiviral medicine used to treat complicated and potentially life-threatening influenza (flu) caused by either the influenza A or B virus in adults and children from 6 months of age. Complicated influenza is a severe flu infection that requires hospitalisation of the patient.

The medicine is used when the virus is resistant to other flu treatments or when other antiviral treatments, including inhaled zanamivir are not suitable for the patient.

Dectova contains the active substance zanamivir.

How is Dectova used?

Dectova is given as an infusion (drip) into a vein. The recommended dose for adults is 600 mg twice daily for 5 to 10 days while for children the dose is adjusted based on weight. Lower doses are given to adults and children with reduced kidney function.

Treatment is started as soon as possible and usually within 6 days after symptoms start.

Dectova can only be obtained with a prescription. For more information about using Dectova, see the package leaflet or contact your doctor or pharmacist.

How does Dectova work?

The active substance in Dectova, zanamivir, prevents the flu virus from spreading by blocking some of the enzymes on the surface of the virus called neuraminidases. When the neuraminidases are blocked, the virus cannot spread. Dectova works on neuraminidases of both influenza A (the most common type) and influenza B viruses.

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What benefits of Dectova have been shown in studies?

Dectova has been shown to work as well as Tamiflu (the standard of care for complicated flu) in one main study involving 626 patients who had been hospitalised. The main measure of effectiveness was how long it took for patients to leave hospital or for 4 out of the following 5 flu symptoms to resolve: fever, decreased levels of oxygen in the blood, raised breathing rate, raised heart rate and abnormal blood pressure. It took around 5.1 days for symptoms to resolve or patients to leave the hospital with Dectova compared with 5.6 days with Tamiflu.

Although Tamiflu was used as the comparator, there is some uncertainty about how effective this medicine is in complicated influenza as it has not been compared with placebo (a dummy treatment) in hospitalised influenza patients.

Further evidence on benefits of Dectova comes from supporting clinical studies and other laboratory studies.

What are the risks associated with Dectova?

The most common side effects with Dectova (which may affect up to 1 in 10 people) are diarrhoea, raised levels of transaminases (liver enzymes), liver injury and rash. The most serious side effect is liver injury.

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

Why is Dectova authorised in the EU?

A main study showed that Dectova works as well as Tamiflu, with comparable time to discharge patients from hospital or resolution of most of the influenza symptoms. Evidence from laboratory and other clinical studies also supported the effectiveness of Dectova.

Dectova is expected to be effective against some flu strains that do not respond to other flu treatments. Its side effects, the most important one being liver injury, are similar to those seen with Tamiflu.

The European Medicines Agency therefore decided that Dectova's benefits are greater than its risks and it can be authorised for use in the EU.

However, because uncertainties remain about the size of the effect of Tamiflu (and by extension the size of Dectova's effect), Dectova has been authorised under 'exceptional circumstances'. Every year, the Agency will review any new information that becomes available and this overview will be updated as necessary.

What information is still awaited for Dectova?

Since Dectova has been authorised under exceptional circumstances, the company that markets the medicine will conduct two observational studies in patients with complicated influenza to obtain further data on the effectiveness.

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

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

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

Other information about Dectova

Dectova received a marketing authorisation valid throughout the EU on 26 April 2019.

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

This overview was last updated in 04-2019.