EMA/205963/2019
EMEA/H/C/003717

Ebilfumin (*oseltamivir*)

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

What is Ebilfumin and what is it used for?

Ebilfumin is an antiviral medicine used to treat or prevent influenza (flu).

- To treat flu, it can be used in adults and children (including full-term newborns) who have the symptoms of flu, when the flu virus is circulating in the community;
- To prevent flu, it can be used in adults and children over 1 year of age who have been in contact with someone who has flu and flu is circulating in the community. This is generally done on a case-by-case basis. Ebilfumin can also be used as preventative treatment in exceptional cases, for instance when the seasonal flu vaccine may not provide sufficient protection and when there is a pandemic (a global epidemic of flu). During a flu pandemic, Ebilfumin can also be used to prevent flu in babies below 1 year of age.

Ebilfumin does not replace flu vaccination, and its use should be based on official recommendations.

Ebilfumin contains the active substance oseltamivir. It is a 'generic medicine'. This means that Ebilfumin contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Tamiflu. For more information on generic medicines, see the question-and-answer document here.

How is Ebilfumin used?

Ebilfumin is available as capsules (30 mg, 45 mg, and 75 mg).

In the treatment of flu, Ebilfumin must be started within two days of the onset of symptoms. The usual dose for adults and children weighing more than 40 kg is 75 mg given twice a day for 5 days. For adults with a weakened immune system (the body's natural defences), it is given for 10 days.

In the prevention of flu, Ebilfumin must be started within two days of contact with someone who has flu. The usual dose for adults and children weighing more than 40 kg is 75 mg given once a day for 10 days after contact with an infected person. When Ebilfumin is used during a flu epidemic, it is given for up to 6 weeks.

For children who weigh less than 40 kg, the dose is calculated according to the child's weight.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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

How does Ebilfumin work?

The active substance in Ebilfumin, oseltamivir, acts on the flu virus, blocking some of the enzymes on its surface known as neuraminidases. When the neuraminidases are blocked, the virus cannot spread. Oseltamivir works on the neuraminidases of both influenza-A (the most common type) and influenza-B viruses.

How has Ebilfumin been studied?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Tamiflu, and do not need to be repeated for Ebilfumin.

As for every medicine, the company provided studies on the quality of Ebilfumin. The company also carried out a study that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of Ebilfumin?

Because Ebilfumin is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Ebilfumin authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Ebilfumin has been shown to have comparable quality and to be bioequivalent to Tamiflu. Therefore, the Agency's view was that, as for Tamiflu, the benefit of Ebilfumin outweighs the identified risk and it can be authorised for use in the EU.

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

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

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

Other information about Ebilfumin

Ebilfumin received a marketing authorisation valid throughout the EU on 22 May 2014.

Further information on Ebilfumin can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/ebilfumin. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 04-2019.