20 March 2014
EMA/CHMP/66668/2014
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Ebilfumin

oseltamivir

On 20 March 2014 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ebilfumin 30 mg, 45 mg and 75 mg, hard capsules intended for the treatment and prevention of influenza. The applicant for this medicinal product is Actavis Group PTC ehf. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Ebilfumin is oseltamivir (as phosphate), a neuraminidase inhibitor, ATC Code: J05AH02. Oseltamivir phosphate is a pro-drug of the active metabolite (oseltamivir carboxylate). The active metabolite is a selective inhibitor of influenza virus neuraminidase enzymes, which are glycoproteins found on the virion surface. Viral neuraminidase enzyme activity is important both for viral entry into uninfected cells and for the release of recently formed virus particles from infected cells, and for the further spread of infectious virus in the body.

Ebilfumin is a generic of Tamiflu which has been authorised in the EU since 20 June 2002. Studies have demonstrated the satisfactory quality of Ebilfumin, and its bioequivalence with the reference product Tamiflu. A question and answer document on generic medicines can be found here.

A pharmacovigilance plan for Ebilfumin will be implemented as part of the marketing authorisation.

The approved indication is:

Treatment of influenza

- In patients one year of age and older who present with symptoms typical of influenza, when influenza virus is circulating in the community.
- Ebilfumin is indicated for the treatment of infants less than 1 year of age during a pandemic influenza outbreak (see section 5.2 of the SmPC). The treating physician should take into

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued 67 days from adoption of the opinion.

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account the pathogenicity of the circulating strain and the underlying condition of the patient to ensure there is a potential benefit to the child.

Prevention of influenza

- Post-exposure prevention in individuals 1 year of age or older following contact with a clinically diagnosed influenza case when influenza virus is circulating in the community.
- The appropriate use of Ebilfumin for prevention of influenza should be determined on a case by case basis by the circumstances and the population requiring protection. In exceptional situations (e.g. in case of a mismatch between the circulating and vaccine virus strains, and a pandemic situation) seasonal prevention could be considered in individuals one year of age or older.
- Ebilfumin is indicated for post-exposure prevention of influenza in infants less than 1 year of age during a pandemic influenza outbreak (see section 5.2 of the SmPC).

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR), and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Ebilfumin and therefore recommends the granting of the marketing authorisation.