EMA/CHMP/851518/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Dectova

zanamivir

On 28 February 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation under exceptional circumstances[2] for the medicinal product Dectova, intended for the treatment of complicated and potentially life-threatening influenza. The applicant for this medicinal product is GlaxoSmithKline Trading Services Limited.

Dectova will be available as a 10 mg/ml solution for infusion. The active substance of Dectova is zanamivir, an inhibitor of influenza virus neuraminidase (ATC code: J05AH01), an enzyme important for viral entry into uninfected cells and release and spread of new virus once cells have been infected.

The benefits with Dectova are its ability to speed resolution of clinical signs and recovery in patients with complicated and potentially life-threatening influenza. The most common side effects are diarrhoea, hepatic transaminases elevations, hepatocellular injury and rash.

The full indication is:

"Dectova is indicated for the treatment of complicated and potentially life-threatening influenza A or B virus infection in adult and paediatric patients (aged ≥6 months) when:

- The patient's influenza virus is known or suspected to be resistant to anti-influenza medicinal products other than zanamivir, and/or
- Other anti-viral medicinal products for treatment of influenza, including inhaled zanamivir, are not suitable for the individual patient.

Dectova should be used in accordance with official guidance."

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 made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[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

[2] In exceptional circumstances, an authorisation may be granted subject to certain specific obligations, to be reviewed annually. This happens when the applicant can show that they are unable to provide comprehensive data on the efficacy and safety of the medicinal product, due to the rarity of the condition it is intended for, limited scientific knowledge in the area concerned, or ethical considerations involved in the collection of such data.

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