Prescribing information

Please consult the Summary of Product Characteristics (SPC) before prescribing

Dectova▼ (zanamivir) solution for infusion. Each vial contains 200mg of zanamivir in 20mL and 3.08mmol (70.8mg) sodium.

Uses: Treatment of complicated and potentially life-threatening influenza A or B virus infections in adults and paediatric patients (aged ≥6months) when: influenza virus is known or suspected to be resistant to anti-influenza agents other than zanamivir, and/or other anti-viral agents for treatment of influenza, including inhaled zanamivir, are not suitable for the individual patient. Dectova should be used in accordance with official recommendations.

Dosage and administration: Treatment should commence as soon as possible and usually within 6 days of the onset of symptoms of influenza. *Adults*: Recommended dose is 600mg twice daily for 5 to 10 days given by intravenous infusion. *Paediatric population*: Adolescents, children and infants should receive a weight-based dose regimen for 5 to 10 days. 6 months to < 6 years: 14mg/kg twice daily; ≥6years to < 18 years: 12mg/kg twice daily up to a maximum dose of 600mg twice daily. The safety and efficacy of Dectova in children aged under 6 months have not been established. *Elderly:* No dose adjustment is required based on age. *Renal impairment: Adults* and children (aged 6 years and over with a body weight of 50 kg or above) with creatinine clearance (CLcr) or clearance by continual renal replacement therapy (CLCRRT) < 80 mL/min should receive an initial 600 mg dose followed by twice-daily maintenance dosing according to their renal function. Dectova is administered by intravenous infusion over 30 minutes.

Contra-indications: Hypersensitivity to the active substances or to any of the excipients.

Special warnings and precautions: *Renal impairment:* All patients must have their renal function assessed before and regularly during treatment. Dectova when administered intravenously must be reduced in patients with renal impairment. *Serious hypersensitivity reactions:* If any hypersensitivity reaction occurs during infusion of Dectova the infusion must be stopped immediately, and appropriate management should be instituted. *Neuropsychiatric events:* Influenza can be associated with a variety of neurological and behavioural symptoms. Patients should be closely monitored for behavioural changes and the benefits and risks of continuing treatment should be carefully evaluated for each patient. *Resistance in immunocompromised patients:* Monitor for resistance and consider switching to alternative therapies where appropriate.

Incompatibilities: Dectova must not be mixed with other medicinal products except sodium chloride 9 mg/mL (0.9%) solution for injection. Dectova should not be administered simultaneously with other intravenous medicinal products or prepared in solutions containing glucose or other electrolytes.

Interactions: Potential for interaction with other medicines is low, based on the known elimination pathway of zanamivir. There was no evidence of interactions with oral oseltamivir in a clinical study.

Ability to drive and use machinery: Dectova has no or negligible influence on the ability to drive or use machines.

Pregnancy and lactation: There is limited data from the use of Dectova in pregnant women. The use of Dectova in pregnancy should only be considered if the possible benefit to the patient is thought to outweigh any possible risk to the foetus. It is unknown whether Zanamivir is excreted in human milk**.**

Side effects: See SPC for full details. Common: Diarrhoea, alanine aminotransferase and/or aspartate aminotransferase elevations, hepatocellular injury, rash. Serious: Oropharyngeal oedema, facial oedema, anaphylactic/anaphylactoid reactions, hallucinations, delirium, convulsions, depressed level of consciousness, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis.

Legal category: POM.

Presentation and basic NHS cost: Dectova is available in a pack size of 1 vial = £27.83. **MA numbers:** EU/1/18/1349/001 **MA holder:** GlaxoSmithKline Trading Services Limited, 12

Riverwalk, Citywest Business Campus, Dublin 24, Ireland. **Further information is available from:** Customer Contact Centre, GlaxoSmithKline, Stockley Park West, Uxbridge, Middlesex UB11 1BT; customercontactuk@gsk.com; Freephone 0800 221 441. Dectova is a trademark of the GlaxoSmithKline group of companies. **Date of preparation:** October 2019. **Ref:** PI-2867 (V2.0)

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard, or search for MHRA yellow card in the Google Play or Apple App store. Adverse events should also be reported to GlaxoSmithKline on 0800 221 441.