Dectova ▼ (zanamivir) PRESCRIBING INFORMATION

Please find below:

1. **PRESCRIBING INFORMATION for Great Britain (GB)**
2. **PRESCRIBING INFORMATION for Northern Ireland (*which is located below the GB Prescribing Information*)**

PRESCRIBING INFORMATION - Great Britain

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

Dectova ▼ (zanamivir) 10mg/ml solution for infusion. Composition: 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 ≥6 months) 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. To be used in accordance with official recommendations.

Dosage and administration: Commence as soon as possible and usually within 6 days of symptom onset. *Adults*: 600mg twice daily for 5 to 10 days by intravenous infusion. *Paediatric population*: weight-based dose regimen for 5 to 10 days: 6 months to <6 years: 14mg/kg twice daily; ≥6 years to <18 years: 12mg/kg twice daily up to a maximum dose of 600mg twice daily. No data <6 months. *Elderly:* No dose adjustment is required based on age. *Renal impairment*: those aged ≥6 years weighing ≥50 kg with creatinine clearance (CLcr) or clearance by continual renal replacement therapy (CLCRRT) <80 mL/min: 600mg dose followed by twice-daily maintenance dosing according to renal function (see SPC for age 6-18 years weighing <50kg, age 6 months to <6 years weighing ≥42.8kg and age 6 months to <6 years weighing <42.8kg). Administer 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:* Dose to be reduced in patients with renal impairment and renal function assessed before and during treatment. *Serious hypersensitivity reactions:* infusion must be stopped immediately, and appropriate management should be instituted. *Neuropsychiatric events:* Influenza can be associated with neurological and behavioural symptoms: monitor for behavioural changes and weigh benefits and risks of continuing treatment. *Resistance in immunocompromised:* Monitor for resistance and consider switching to alternative therapies where appropriate. Clinical data are limited. Not shown to reduce bacterial complication risk. Contains 70.8mg sodium.

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

Interactions: Potential for interaction is low, based on the known elimination pathway of zanamivir. No evidence of interactions with oral oseltamivir.

Pregnancy and lactation: Limited data in pregnant women do not indicate harm and unknown if excreted in human milk: only consider if benefit to the patient outweighs risk to foetus/child.

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, hepatocellular injury.

Legal category: POM. **Presentation and basic NHS cost:** Pack size of 1 vial = £27.83. **MA numbers:** PLGB 19494/0292 **MA holder:** GlaxoSmithKline UK Limited, 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom. **Further information is available from:** GlaxoSmithKline Customer Contact Centre: customercontactuk@gsk.com; Freephone 0800 221 441. Dectova is a trademark of the GlaxoSmithKline group of companies.

Date of preparation: December 2023.

Ref: PI-2867 (V5).

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk 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.

PRESCRIBING INFORMATION – Northern Ireland

Dectova ▼ (zanamivir) 10mg/ml solution for infusion. Composition: 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 ≥6 months) 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. To be used in accordance with official recommendations.

Dosage and administration: Commence as soon as possible and usually within 6 days of symptom onset. *Adults*: 600mg twice daily for 5 to 10 days by intravenous infusion. *Paediatric population*: weight-based dose regimen for 5 to 10 days: 6 months to <6 years: 14mg/kg twice daily; ≥6 years to <18 years: 12mg/kg twice daily up to a maximum dose of 600mg twice daily. No data <6 months. *Elderly:* No dose adjustment is required based on age. *Renal impairment:* those aged ≥6 years weighing ≥50 kg with creatinine clearance (CLcr) or clearance by continual renal replacement therapy (CLCRRT) <80 mL/min: 600mg dose followed by twice-daily maintenance dosing according to renal function (see SPC for age 6-18 years weighing <50kg, age 6 months to <6 years weighing ≥42.8kg and age 6 months to <6 years weighing <42.8kg). Administer 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:* Dose to be reduced in patients with renal impairment and renal function assessed before and during treatment. *Serious hypersensitivity reactions:* infusion must be stopped immediately, and appropriate management should be instituted. *Neuropsychiatric events:* Influenza can be associated with neurological and behavioural symptoms: monitor for behavioural changes and weigh benefits and risks of continuing treatment. *Resistance in immunocompromised:* Monitor for resistance and consider switching to alternative therapies where appropriate. Clinical data are limited. Not shown to reduce bacterial complication risk. Contains 70.8mg sodium.

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

Interactions: Potential for interaction is low, based on the known elimination pathway of zanamivir. No evidence of interactions with oral oseltamivir.

Pregnancy and lactation: Limited data in pregnant women do not indicate harm and unknown if excreted in human milk: only consider if benefit to the patient outweighs risk to foetus/child.

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, hepatocellular injury.

Legal category: POM. **Presentation and basic NHS cost:** 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:** GlaxoSmithKline Customer Contact Centre: customercontactuk@gsk.com; Freephone 0800 221 441. Dectova is a trademark of the GlaxoSmithKline group of companies.

Date of preparation: December 2023.

Ref: PI-2867 (V5.0).

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