Prescribing information

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

Relenza 5mg/dose, Zanamivir, pre-dispensed, inhalation powder. **Indications**: Treatment and post-exposure prophylaxis of influenza A & B in adults and children (≥ 5 years) who present with symptoms typical of influenza when influenza is circulating in the community and following contact with a clinically diagnosed case in a household. Relenza is not a substitute for influenza vaccination.

Dosage and administration: Other inhaled drugs, e.g. asthma medication, should be administered prior to administration of Relenza. *Treatment*: begin as soon as possible, within 48 hours after onset of symptoms for adults, and within 36 hours after onset of symptoms for children. 2 inhalations (2x5mg) twice daily for five days, providing a total daily dose of 20 mg. *Post-exposure prophylaxis*: 2 inhalations (2x5mg) once daily for 10 days starting within 36hrs of exposure to an infected person. Administration by oral inhalation only, using the Diskhaler device provided.

Contraindications: Hypersensitivity to the active substance ingredient and in patients with milk protein allergy.

Precautions: Those with galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine. Due to the limited number of patients with severe asthma or with other chronic respiratory disease, patients with unstable chronic illnesses or immunocompromised patients who have been treated, it has not been possible to demonstrate the efficacy and safety of Relenza in these groups. Rare reports of bronchospasm/decline in respiratory function in those with history of respiratory disease- discontinue treatment and seek medical advice. Efficacy of Relenza has not been established in the elderly (≥65years). Patients with influenza should be monitored for neuropsychiatric events during administration of Relenza, especially children and adolescents. Must not be used for nebulisation or mechanical ventilation. **Interactions:** Clinically significant interactions are unlikely.

Pregnancy & lactation: As a precautionary measure, it is preferable to avoid the use of Relenza during pregnancy, unless clinical conditions is such that the potential benefits to the mother significantly outweigh the possible risk to the foetus. There is no information on secretion of Zanamivir into human breast milk. A risk to the breastfed child cannot be excluded.

Adverse Reactions: See SPC for full details. *Common:* Rash. *Uncommon:* Allergic-type reactions including oropharyngeal oedema, vasovagal-like reactions, bronchospasm, dyspnoea, throat tightness or constriction, urticaria. *Rare:* anaphylactic reactions, facial oedema, severe skin reactions including erythema multiforme, Stevens Johnson syndrome, and Toxic epidermal necrolysis. *Other:* Convulsions and neuropsychiatric events (mainly in children and adolescents).

Legal Category: POM. **MA number**: PL 10949/0327. **Presentation and basic NHS cost**: 5 foil disks and plastic diskhaler. NHS cost: £16.36 / 5 disks. **MA holder**: Glaxo Wellcome UK Ltd trading as GlaxoSmithKline UK, GSK Medicines Research Centre, Gunnels Wood Road, Stevenage, Hertfordshire, SG1 2NY, U.K..

Further information is available from: Customer Contact Centre, GlaxoSmithKline; customercontactuk@gsk.com; Freephone 0800 221 441. Trademarks are owned by or licensed to the GSK group of companies.

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