

15 October 2009



**IMPORTANT SAFETY WARNING**

**Relenza 5mg/dose, inhalation powder, pre-dispensed  
(PA 1077/11/1)  
Relenza Rotacaps  
MUST NOT BE NEBULIZED**

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Dear Healthcare Provider:

GlaxoSmithKline (GSK) has received a report of the death of a patient with influenza who received Relenza 5mg/dose, inhalation powder, pre-dispensed which was solublized and administered by mechanical ventilation. GSK is aware that Relenza 5mg/dose, inhalation powder, is being removed from its approved packaging and dissolved in various solutions for the purpose of nebulizing zanamivir for inhalation by patients with influenza who are unable to take oral medications or unable to inhale Relenza 5mg/dose, inhalation powder using the Diskhaler or Rotacaps.

- **Relenza 5mg/dose, inhalation powder is not intended to be reconstituted in any liquid formulation and is not recommended for use in any nebulizer or mechanical ventilator.**
- **This applies to all presentations of lactose-containing zanamivir inhalation powder (Relenza Diskhaler or Rotacaps).**
- **Relenza or zanamivir for nebulization has not been approved by any regulatory authority and the safety, effectiveness and stability of zanamivir use by nebulization have not been established.**

The death referenced above was of a pregnant woman on mechanical ventilation who received zanamivir solution made from dry powder product from Relenza Rotadisks via nebulizer for three days. Death was attributed to obstruction of the ventilator. The reporting physician believed that the obstruction in the ventilator was due to stickiness caused by lactose (from Relenza 5mg/dose, inhalation powder) in the nebulizing solution.

Relenza 5mg/dose, inhalation powder should only be used as directed in the prescribing information by using the Diskhaler or Rotacaps devices provided with the drug product. Relenza 5mg/dose, inhalation powder is a mixture of zanamivir active drug substance (5 mg) and lactose drug carrier (20 mg). This formulation is not designed or intended to be administered by nebulization. There is a risk that the lactose sugar in this formulation can obstruct proper functioning of mechanical ventilator equipment.

Although an investigational aqueous formulation for nebulizer delivery was briefly explored during early development of zanamivir and may be mentioned in some descriptions or publications of those early-phase studies, that formulation was not developed further and did not use the lactose-based powder contained in the marketed Relenza product.

Please refer to the currently approved Summary of medicinal Product Characteristics for Relenza on the **Pandemic (H1N1) 2009 Medicines Information and Reporting** page of the IMB website, [www.imb.ie](http://www.imb.ie).

You can assist us in monitoring the safety of Relenza by reporting adverse reactions and medication errors:

- to us at GlaxoSmithKline (Ireland) Ltd., Stonemasons Way, Rathfarnham, Dublin 18 (Freephone 1800 244 255, Fax 01 4938839 or e-mail [ireland.drugsurveillance@gsk.com](mailto:ireland.drugsurveillance@gsk.com))
- or to Irish Medicines Board using the on-line reporting system through [www.imb.ie](http://www.imb.ie) or alternatively to the Pharmacovigilance Section, Irish Medicines Board, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2 (Telephone 01 676 4971 or 01 676 4976, Fax 01 676 7836).

If you have any questions or require additional information concerning Relenza, please contact the GlaxoSmithKline (Ireland) Ltd., Stonemasons Way, Rathfarnham, Dublin 18 (Freephone 1800 244 255).

Sincerely,



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VP and Area Medical Director, North West Europe  
GlaxoSmithKline Pharmaceuticals