



**Australian Government**  
**Department of Health and Ageing**  
**Therapeutic Goods Administration**

Dear Health Care Professional,

**Relenza (zanamivir) Safety Advisory**

The Therapeutic Goods Administration (TGA) has been advised by the US Food and Drug Administration (FDA) of a reported death of a patient who had received Relenza (zanamivir) Inhalation Powder that had been solubilized and administered by mechanical ventilation.

The sponsor GlaxoSmith Kline (GSK) advised the USFDA that it is aware of cases in which the Relenza Inhalation Powder is being removed from its approved packaging and dissolved in various solutions for use via nebuliser in patients unable to take oral medications or inhale Relenza using the Diskhaler.

Health care practitioners are reminded that Relenza (zanamivir) Inhalation Powder is not intended to be reconstituted in any liquid formulation and is not recommended for use in a nebuliser or mechanical ventilator.

The safety, effectiveness, and stability of zanamivir use by nebulisation have not been established and the use of the product via nebuliser has not been approved by the TGA.

In the case reported above, death was attributed to obstruction of the ventilator, thought to be due to stickiness caused by lactose in the nebuliser solution. The formulation of Relenza is not designed or intended to be administered by nebuliser as there is a risk that the lactose sugar in this formulation may obstruct proper functioning of mechanical ventilator equipment.

Relenza Inhalation Powder should only be used as directed in the approved Product Information, and administered via the Diskhaler device in which the product is supplied.

Further information is available at this link

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm186081.htm>

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