

Dear Colleague,

RELENZA (ZANAMIVIR) INHALATION POWDER MUST NOT BE DISSOLVED FOR ADMINISTRATION VIA NEBULISER

I am writing to advise you that the antiviral drug Relenza (zanamivir) should not be reformulated from its intended inhalation powder into a solution to be nebulised. This advice follows an incident outside of the UK involving a patient who died when this unlicensed formulation caused a blockage in a mechanical ventilator.

Relenza (zanamivir) is available in the UK as a licensed powder for inhalation via a diskhaler device. Licensed use of Relenza via this device remains safe and this new advice does not affect the recommendations for use of the licensed formulation.

The Medicines and Healthcare products Regulatory Agency (MHRA) has now become aware that there may be limited unlicensed practice in the UK whereby the licensed inhalation powder formulation is removed from its approved packaging and dissolved for the purpose of nebulising zanamivir for inhalation.

This practice has resulted in a fatality in a patient on mechanical ventilation who received zanamivir solution reformulated in this way and administered via nebuliser for three days. Death was attributed to obstruction of the ventilator. It is believed that the obstruction in the ventilator was caused by solubilised lactose (from the powder formulation) in the nebulising solution.

I would like to remind prescribers that Relenza inhalation powder should only be used as directed in the prescribing information by using the Diskhaler device provided with the product.

Sir Gordon Duff
Chairman, Commission on Human Medicines