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DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Dectova ▼ (zanamivir hydrate) solution for infusion 10mg/mL:

Important information for Healthcare Professionals about the expiry date of certain batches

Dear Healthcare Professional,

Summary

GlaxoSmithKline (GSK) is currently experiencing interruption in the UK supply of Dectova (zanamivir hydrate) solution for infusion 10mg/mL for the treatment of complicated and potentially life-threatening influenza A or B virus infection in adult and paediatric patients (aged ≥ 6 months) when:

• The patient's influenza virus is known or suspected to be resistant to anti-influenza medicinal products other than zanamivir, and/or

• Other anti-viral medicinal products for treatment of influenza, including inhaled zanamivir, are not suitable for the individual patient.

To ensure continuity of supply, GSK has obtained approval from the Medicines and Healthcare products Regulatory Agency (MHRA) to extend the expiry date of certain batches of Dectova (zanamivir hydrate) solution for infusion 10mg/mL (see Table 1). This does not have any impact on quality, efficacy or safety of the product.

Action required by Healthcare Professionals

- You should read the complete information in this letter and cascade it to relevant teams to ensure they are using Dectova (zanamivir hydrate) according to its authorised conditions.
- There have been no changes to the therapeutic indications (See summary above) or special precautions for storage (Table 2) for vials of Dectova (zanamivir hydrate) solution for infusion 10mg/mL. Please consult the full Summary of Product Characteristics for further details (https://www.medicines.org.uk/emc/product/10193/smpc).
- The extension of shelf life for the specific batches listed in Table 1 does not have any impact on quality, efficacy or safety of the product.
- Be aware that there may be a period where batches of Dectova (zanamivir hydrate) solution for infusion 10mg/mL with 60-month shelf life and this extended 72-month shelf life may both co-exist on the market for a period of time.

Table 1: Approved batch numbers of the affected packs of Dectova (zanamivir hydrate) solution for infusion 10mg/mL

Dectova (zanamivir hydrate)	Batch number	Expiry date stated on vial	Updated MHRA approved expiry date
Solution for infusion 10mg/mL 1 x 20mL	CX9K	31/10/2024	31/10/2025
Solution for infusion 10mg/mL 1 x 20mL	PN2B	31/10/2024	31/10/2025
Solution for infusion 10mg/mL 1 x 20mL	V99Y	31/10/2024	31/10/2025

Supporting Information

Table 2: Special precautions for storage are unchanged for Dectova (zanamivir hydrate) solution for infusion 10mg/mL

After Dilution	From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should not be longer than 24 hours at 2° C to 8° C, unless dilution has taken place in controlled and validated aseptic conditions.

Call for reporting

Dectova ▼ (zanamivir hydrate) is subject to additional monitoring. This will allow quick identification of new safety information.

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the Yellow Card website: **https://yellowcard.mhra.gov.uk**
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

Adverse events should also be reported to GlaxoSmithKline on 0800 221 441 or UKSafety@gsk.com

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

Company contact point:

Should you have any questions or require additional information, please contact the GSK Medical Information Department on 0800 221 441, 8:30am to 5:00pm GMT, Monday – Friday, or email ukmedinfo@gsk.com.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients as necessary.

Electronically signed by: Dr Hubert Bland
Reason: I am signing for the reasons as stated in the document.
Date: Jan 16. 2025 10:42 GMT

Dr Hubert Bland MBChB FFPM
Country Medical Director, GSK UK