gsk.com

79 New Oxford Street
London
WC1A 1DG

January 2025

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Dectova ▼ (zanamivir hydrate) solution for infusion 10mg/mL:
Interim supply of EU Shared Pack stock to mitigate United Kingdom (UK) supply disruption

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 in supply, GSK has obtained approval from the Medicines and Healthcare products Regulatory Agency (MHRA) to supply zanamivir hydrate destined for EU Markets (Germany, France, Ireland, Malta, Netherlands and Northern Ireland) (Original destination country, product strength, batch number/ size and expiry dates summarised in a table at end of this letter), which is expected to be on the UK market during January 2025.

Please note the following:

- Product from the EU Shared Pack (Germany, France, Ireland, Malta, Netherlands and Northern Ireland) is considered licenced in UK.
- Product from the EU Shared Pack has the same formulation as the UK product and is manufactured according to the same manufacturing process and quality controls as the UK product.
- There is a current temporary interruption in the UK supply of Dectova (zanamivir hydrate) solution for infusion 10mg/mL, due to high demand and incapacity to supply more packs in the short term.
- The EU Shared Pack outer box does not contain an anti-tamper evidence seal, compared to the UK packaging.
- Discard the multi-language Patient Information Leaflet (PIL) contained within the EU Shared Pack.
- Refer to the UK approved PIL which is to be supplied electronically, via e-mail.
- For copies of the UK PIL, or to access the Summary of Product Characteristics (SmPC), please refer to https://www.medicines.org.uk/emc/product/10193/smpc or contact the GSK Medical Information Department at ukmedinfo@gsk.com.
- The MHRA has agreed to an exemption granted in accordance with regulation 266(4)(a) and (b) of the Human Medicines Regulations (HMR) 2012 and Article 63(3) of Council Directive 2001/83/EC, from the obligation that certain particulars should appear on the outer and immediate packaging of Dectova and that the information must be given in English.

This letter is intended to provide you, the Healthcare Professional, with information about the arrangements concerning the MHRA approval of supply of the EU Shared Pack to the UK.

gsk.com

79 New Oxford Street
London
WC1A 1DG

Please refer to the UK Summary of Product Characteristics (SmPC) for Dectova (zanamivir hydrate) solution for infusion before prescribing.

The original destination countries, product strength, batch number/ size and expiry dates of the EU Shared pack are as follows:

Original destination countries	Product Strength	Batch Number	Batch Size	Expiry
EU Shared Pack (Germany, France, Netherlands, Ireland, Malta and Northern Ireland)	10mg/mL (20mL)	3D3N	1000	31.08.2025

Call for reporting

▼ This medicine 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.

[Signature]

Electronically signed by: Dr Hubert Bland
Reason: I am approving the content of this document and authorize its issuance.
Date: Jan 9, 2025 14:27 GMT

Dr Hubert Bland MBChB FFPM
Country Medical Director, GSK UK