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GLAXOSMITHKLINE ADVISORY

Date: 09/12/2024

Dear Healthcare Professional,

Title: Xevudy®▼ (sotrovimab) 500 mg concentrate for solution for infusion: Important information for healthcare professionals about the expiry date of all packs

Summary

- **The Medicines and Healthcare products Regulatory Agency (MHRA) has approved a further extension to the expiry date of Xevudy (sotrovimab) 500 mg concentrate for solution for infusion, for the specified batches detailed below (see Table 1).**
- **Please read the complete information in this letter and cascade it to relevant teams to ensure they are using Xevudy (sotrovimab) according to its authorised conditions.**

GlaxoSmithKline UK Limited would like to advise you that an additional Batch Specific Variation (BSV) to extend the expiry date of cartons and vials of Xevudy (sotrovimab) 500 mg concentrate for solution for infusion, has been approved by the MHRA (see Table 1).

Action required by Health Care Professionals

- You should read the complete information in this letter and cascade it to relevant teams to ensure they are using Xevudy (sotrovimab) according to its authorised conditions.
- There have been no changes to the therapeutic indications or special precautions for storage (Table 2) for vials of Xevudy (sotrovimab) 500 mg concentrate for solution for infusion. These have been included below for completeness. Please consult the full Summary of Product Characteristics for further details.

Table 1: BSV approved batch numbers of the affected cartons and vials of Xevudy (sotrovimab) 500 mg concentrate for solution for infusion

Xevudy (sotrovimab)	Batch number	Expiry date stated on vial	Updated MHRA approved expiry date
500 mg of sotrovimab in 8 mL (62.5 mg/mL)	U26X	Jan-2023	31-July-2025
500 mg of sotrovimab in 8 mL (62.5 mg/mL)	SP5C	Jan-2023	31-July-2025
500 mg of sotrovimab in 8 mL (62.5 mg/mL)	2F6G	Feb-2023	31-Aug-2025

Supporting Information

Table 2: Special precautions for storage

Item	MHRA Conditional Marketing Authorisation for Xevudy (sotrovimab)
Unopened carton/vial	Store in a refrigerator (2°C to 8°C). Do not freeze. Store in the original carton in order to protect from light.
Diluted solution for infusion	The diluted solution is intended to be used immediately. If after dilution, immediate administration is not possible, the diluted solution may be stored at room temperature (up to 25°C) for up to 6 hours or refrigerated (2°C to 8°C) for up to 24 hours from the time of dilution until the end of administration.

Call for reporting

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report ANY suspected adverse reactions. Suspected adverse drug reactions should be reported to the MHRA through the Yellow Card scheme.

Adverse events should be reported. Reporting forms and information can be found at https://coronavirus-yellowcard.mhra.gov.uk/ or search for MHRA Yellowcard in the Google Play or Apple App Store. Adverse events should also be reported to GlaxoSmithKline on 0800 221 441.

As Xevudy (sotrovimab) is a biological medicine, healthcare professionals should report adverse reactions by brand name and batch number. When reporting please provide as much information as possible, including information about medical history, any concomitant medications, onset, treatment dates, and product brand name and batch number. Thank you in advance for your cooperation with this additional information.

Contact for Further Information or Questions

For all questions, please contact the GSK Medical Information Department on 0800 221 441 or via email at medical.information@gsk.com

Yours faithfully,

HBland

Dr Hubert Bland
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GSK