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Dear Healthcare Professional Letter
Effective date: 18th January 2023

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GLAXOSMITHKLINE ADVISORY

Date: 18th January 2023

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

Key Messages

- **The MHRA has approved a further six months extension of 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 ensure it is cascaded to the relevant teams to ensure they are using the authorised conditions**

GlaxoSmithKline UK Limited would like to inform 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 Medicines and Healthcare products Regulatory Agency (MHRA).

Action required by Health Care Professionals/Investigators

- Please read the complete information in this letter and ensure it is cascaded to the relevant teams to ensure they are using the authorised conditions.
- This variation has not been applied to batches that expired in October 2022 and these batches should therefore no longer be used.
- There have been no changes to the authorised indications (see Table 2 overleaf) or in-use storage conditions (Table 3) for vials of Xevudy (sotrovimab) 500 mg concentrate for solution for infusion, these have been included for completeness.

Table 1: BSV approved batches Table 1 details the 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	31-Jan-2023	31-Jul-2023
500 mg of sotrovimab in 8 mL (62.5 mg/mL)	SP5C	31-Jan-2023	31-Jul-2023
500 mg of sotrovimab in 8 mL (62.5 mg/mL)	2F6G	28-Feb-2023	31-Aug-2023

Supporting Information

Key information to be followed within Conditional Marketing Authorisation

Table 2: Key elements of the authorisation for Xevudy (sotrovimab) 500 mg concentrate for solution for infusion.

Item	MHRA Conditional Marketing Authorisation for Xevudy (sotrovimab)
Indication	For the treatment of symptomatic adults and adolescents (aged 12 years and over and weighing at least 40 kg) with acute covid-19 infection who do not require oxygen supplementation and who are at increased risk of progressing to severe covid infection.
Dose	The recommended dose is a single 500 mg intravenous infusion administered following dilution.
Route of Administration	For intravenous use. This medicinal product must be diluted prior to administration. Please consult the SmPC for full details.

Storage conditions

Table 3: Storage times to be followed as per MHRA authorisation

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

Alternatively, please contact Richard Walker, UK COVID-19 Therapeutics Medical Director on +44 7831 550565 or via email at richard.g.walker@gsk.com

Yours faithfully,

David M Brooks, MD, MBA, MPH

Vice President, Country Medical Director UK & Ireland

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