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XEVUDY© **(sotrovimab) Great Britain (GB) Prescribing information**

(Please consult the full Summary of Product Characteristics (SmPC) for GB before prescribing)

XEVUDY© 500 mg concentrate for solution for intravenous (IV) infusion **Presentation:** Each vial contains 500 mg of sotrovimab in 8 mL (62.5 mg/mL). **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-19 infection. **Posology and Method of Administration:** Xevudy should only be administered by a qualified healthcare provider. Administer where management of severe hypersensitivity, such as anaphylaxis, is possible. Monitor individuals during and post IV infusion according to local guidelines. Administer Xevudy within 5 days of onset of COVID-19 symptoms. The recommended dose is a single 500 mg IV infusion administered over 30 minutes following dilution. Consideration should be given to official guidance in the appropriate use of Xevudy. See SmPC for instructions on the preparation, dilution, and infusion of the medicinal product. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Warnings and Precautions:** Recipients are advised to self-isolate in accordance with national COVID-19 guidelines. **Traceability:** To improve traceability of biological medicinal products, clearly record the name and the batch number of administered product. **Hypersensitivity:** Hypersensitivity reactions, including serious reactions such as anaphylaxis, have been reported. If signs and symptoms of severe hypersensitivity occur, discontinue administration immediately and initiate appropriate supportive care. If mild to moderate hypersensitivity reactions occur, consider slowing or stopping the infusion and give appropriate supportive care. **Antiviral resistance:** Decisions regarding the use of sotrovimab should take into consideration what is known about the characteristics of the circulating SARS-CoV-2 viruses including regional or geographical differences and available information on sotrovimab susceptibility patterns. When molecular testing or sequencing data is available, it should be considered to rule out SARS-CoV-2 variants that are shown to have reduced susceptibility to sotrovimab (see sections 5.1 and 5.3 of SmPC). **Special populations:** No dose adjustment is required in elderly patients, patients with hepatic impairment or patients with renal impairment. The safety and efficacy in children under 12 years old or weighing less than 40 kg have not yet been established. **Interactions with other medicinal products:** No interaction studies have been performed. Xevudy is not renally excreted or metabolised by cytochrome P450 (CYP) enzymes; interactions with renally excreted concomitant therapies or substrates, inducers, or inhibitors of CYP enzymes are unlikely. Concomitant administration of sotrovimab with COVID-19 vaccines has not been studied. **Fertility**, **pregnancy, and breast feeding:** No data on human fertility, in pregnant women or on excretion in human milk. The potential treatment benefit or risk of placental transfer of Xevudy to the developing foetus or risk to the newborn or infants via breast-feeding is not known**. Undesirable effects:** The common (≥1/100 to <1/10) adverse reactions were hypersensitivity reactions. Anaphylaxis was rare (≥1/10,000 to <1/1,000). **Storage:** Store in a refrigerator (2°C to 8°C) in the original carton. Do not freeze. Diluted solution is intended for immediate use. If immediate administration is not possible, diluted solution may be stored (room temperature up to 25°C) up to 6 hours or refrigerated (2°C to 8°C) up to 24 hours from the time of dilution until end of administration. **Legal Category:** POM**. Presentation and Basic NHS cost:** Xevudy 1 vial containing 500mg concentrate for solution for infusion - £2209.00. **Marketing Authorisation (MA) Number** PLGB 19494/0301 **MA Holder: GB** GlaxoSmithKline UK Limited 980 Great West Road Brentford Middlesex TW8 9GS United Kingdom **Date of Preparation:** November 2023 PI-12418 © 2023 Trademarks are owned by or licensed to the GSK group of companies.

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.