Sotrovimab Intravenous Medicine for Adults

Who can administer

May be administered by registered competent doctor or nurse/midwife

Important information

- Sotrovimab is a monoclonal antibody (IgG1, kappa) produced in Chinese Hamster Ovary (CHO) cells by recombinant DNA technology
- Only use where **hypersensitivity reactions** such as **anaphylaxis** can be managed
- Restricted **unless approved by Infectious Diseases** and **complies with national criteria**.
- **Re-order formÂ also to be completed as soon as prescribed**Â and forwarded to pharmacy.orders@hse.ieÂ for stock replenishment

Available preparations

XevudyÂ 500mg perÂ 8mL vial

Reconstitution

Already in solutionÂ

- **Must be further diluted before use**
- **Requires careful preparation, see below**

Infusion fluids

Sodium chloride 0.9% or Glucose 5%

Methods of intravenous administration

Intermittent intravenous infusion (using an electronically controlled infusion device)

- This is a monoclonal antibody. **Reduce direct handling to a minimum** and wear appropriate **personal protective equipment**.
- If pharmacy unable to manufacture
  - Remove the vial from the fridge and check it is **free from particulate matter**
  - Allow the vial to reach **room temperature, protectÂ from light**, prior to dilution (about 15 minutes)
  - **Gently swirl** the vial several times before use; do NOT shake as air bubbles may form
  - Withdraw 8mL (500mg) sotrovimab from the vial and add to 100mL sodium chloride 0.9% or glucose 5% infusion bag
  - Gently **rock the bag back and forth** 3 to 5 times. Do NOT invert the bag
  - *Note: There is no need to remove fluid from the bag before adding sotrovimab.*
- **Administer over 30 minutes with a 0.2micron in-line filter (available from pharmacy)**

Dose in adults

Usual doseÂ Â (adults and adolescents (from 12 years and over 40kg body weight))

- Single dose of sotrovimab 500mg

Renal impairmentÂ

- No dose adjustment is required in patients with renal impairment

Monitoring

- Patients should be monitored for one hour post infusion due to the small risk of anaphylaxis and infusion related events (1%)

Further information

As per the national guideline (version 2.0), the patient must be inÂ a group included in Tier 1 or Tier 2 of the Clinical prioritisation Framework for delivery of Novel Therapeutics for COVID 19. Eligible patients include:Â
1.Â Â Â **Unvaccinated** patients at high risk and very high risk of progressing to severe COVID 19 infection (Clinical Prioritisation Framework for the Use and Prescribing of Emerging Novel COVID -19 Therapeutics Tier 1 and Tier 2)Â
2.Â Â Â **Severely immunocompromised** patients at very high risk of progressing to severe COVID 19 infection who despite vaccination are unlikely to have generated protective immunity (Clinical Prioritisation Framework for the Use and Prescribing of Emerging Novel COVID -19 Therapeutics Tier 1)

AND Treatment is initiated **within 5 days of onset of symptoms** of COVID-19 Â
ANDÂ COVID-19 **diagnosis is confirmed with a positive PCR test** result within the last 5 daysÂ
Â Â

- Serology testing COULD be carried out in advance, where locally available, for any patients who despite vaccination are unlikely to have generated protective immunity. However this should not be viewed as a requirement for treatment at this time
- There MAY be logistical or supply constraints that make it impossible to offer the available therapy to all eligible patients in Tier 1 and in Tier 2, making patient TRIAGEÂ necessary. In this situation the patients in the Clinical Prioritisation Framework for the Use and Prescribing of Emerging Novel COVID -19 Therapeutics Tier 1 category with the listed immunocompromised conditions and the unvaccinated should be prioritised
- There is no hierarchy of treatment between remdesivir and sotrovimab at present

Please refer to national protocol when checking suitability for prescribing. Please complete the re-ordering form with patient details and prescribers details and return to pharmacy purchasing ASAP.

Clinical note: The larger dilution volume of 100ml is advised on account of dead-space in lines to minimise the risk of under-dosing (P Kidd)

Storage

Store in a refrigerator (2 to 8^{0}C)

References

1.Â Â Â Xevudy 500mg SPC available on EMC
2.Â Â Injectable medicines guide, downloaded from Medusa 20/01/2022
3.Â Â Â HPRA guide on Sotrovimab
4.Â Â Â National guidance on use and criteria for SotrovimabÂ (email: 18/2/2022)

All references accessed online on 20/1/2022 unless otherwise stated.

Therapeutic classification

Monoclonal antibody