Belimumab Intravenous Infusion for Adults

Who can administer

May be administered by registered competent doctor or nurse/midwife

Important information

- Belimumab is NOT recommended for administration in severe active central nervous system lupus, HIV, a history of/active Hepatitis B or C, hypogammaglobinaemia or IgA deficiency or a history of major organ transplant or hematopoietic stem cell/marrow transplant or renal transplant
- Belimumab should not be initiated in patients with active severe infections (including serious chronic infections).Â Careful consideration should be given to interrupting belimumab in patients who develop an infection while on this treatment, until the infection is resolved
- For other cautions etc- see SPC
- Pneumococcal vaccination should be considered before initiating treatment
- **Infusion reactions** may occur - see under **Monitoring Requirements** below [ref 1]
- **Premedication:** an anti-pyretic and an antihistamine may be administered before each infusion
  - Paracetamol 1g IV (if >50kg, 15mg/kg if <50kg)
  - Chlorphenamine 10mg IV
- In order to improve the traceability of biological medicinal products, **the name and the batch number of the administered product should be clearly recorded**
- See **monitoring requirements** below

Available preparations

Benlysta 120mg vial (concentrate for infusion)
Benlysta 400mg vial (concentrate for infusion)

Reconstitution

Gloves, protective eyewear and a mask should be worn by those handling this drug [ref 1]

Water for injection
1.5mL per 120mg vial
4.8ml per 400mg vial

- Remove vial from the fridge and allow it to warm to room temperature for 10 to 15 minutes
- A 21 to 25 gauge needle is recommended for use when piercing the vial stopper for reconstitution and dilution.
- The stream of water for injection should be directed towards the side of the vial to minimise foaming
- Gently swirl the vial for 60 seconds every 5 minutes until the powder is dissolved. Do not shake
- Reconstitution typically is completed within 10 to 15 minutes, but may take up to 30 minutes
- Once reconstitution is complete, the solution should be opalescent and colourless to pale yellow and without particles.Â Small air bubbles, however, are expected and acceptable
- After reconstitution, the solution contains 80mg belimumub per mL
- Protect the reconstituted solution from sunlight
- The total time from reconstitution to completion of infusion should not exceed 8 hours

Dilute further prior to administration

Infusion fluids

Sodium chloride 0.9% **ONLY**

Methods of intravenous administration

Intermittent intravenous infusion

- Add required dose to 250mL infusion fluid [ref 1)Â]
- Gently invert the bag to mix
- Administer over 60 minutes
- If patient weighs 40kg or less, an infusion bag of 100ml may be used, providing the final concentration does not exceed 4mg/mL,Â
- The infusion rate may be slowed or interrupted if the patient develops an infusion reaction (see under **Monitoring**- below)

Dose in adults

Systemic lupus erythematosus/active lupus nephritis

- Give 10mg/kg on Days 0, 14 and 28, and at 4-week intervals thereafter
- Monitor for improvement after 6 months treatment and consider discontinuation if no improvement in disease control

Elderly patients

- Use with caution in patients 65 years or older, limited data

Renal Impairment

- Use with caution in severe renal impairment, limited data

Hepatic impairment

- Dose adjustment unlikely to be required (but no specific studies have been conducted)

Monitoring

- Monitor for severe or life-threatening hypersensitivity reactions and infusion reactions - stop infusion immediately if the patient develops a potentially life-threatening adverse reaction
- Monitor blood pressure, pulse, respiratory rate and temperature frequently
  - e.g. every 15 minutes initially, then every 30 to 60 minutes if previous observations stable
  - Monitor during and for several hours post-infusion
    - e.g. for 5 hours after at least the first two infusions (taking into account the possibility of a late onset reaction)
    - From the third infusion onwards, monitoring for two hours post infusion may be sufficient (providing no adverse reaction noted post first two doses) [ref 2)]
    - Warn patient that hypersensitivity reactions may occur/reoccur on the day of, or the day after, infusion and to seek immediate medical help if symptoms develop
    - The package leaflet should be provided to the patient each time the drug is administered
- The risk of hypersensitivity is greatest with the first two infusions; however the risk should be considered for every infusion administered.
- Patients with a history of multiple drug allergies or significant hypersensitivity may be at increased risk
- Monitor for symptoms suggestive of PML (e.g., cognitive, neurological or psychiatric symptoms or signs)

during the course of treatment therapy
- Monitor for new or worsening psychiatric symptoms.

Further information

- Management of infusion related reactions: depending on the severity of the reactions, the infusion rate may either be slowed or stopped
- Live vaccines should not be given for 30 days before, or concurrently with belimumab as clinical safety has not been established
- Transition to subcutaneous administration:Â See SPC for details

Storage

Store between 2 and 8^{0}C

Do not freeze

References

SPC November 2022

1: Injectable Drugs guide, downloaded from Medusa 28th June 2023

2: Local expert opinion, email on file June 29th, 2023

Therapeutic classification

Selective immunosuppressants
Humanised monoclonal antibody