Tocilizumab Intravenous for Adults

Who can administer

May be administered by registered competent doctor or nurse/midwife

Important information

- Treatment with Tocilizumab should not be initiated in patients with active severe infections (with the exception of COVID-19)
- Must have access to facilities for managing hypersensitivity reactions including**anaphylaxis.** See QPulse document: Infusion related Patient reaction in nurse-led setting **CLN-NM-0118**
- **Patient alert card** must be provided - Email: ireland.drug_surveillance_centre@roche.com
- **Patient guides** are also available - use the above email contact
- In order to improve the traceability of biological medicinal products, **the name and the batch number of the administered product should be clearly recorded.**

Available preparations

RoActemra 80mg per 4ml vial

RoActemra 200mg per 10ml vial

RoActemra 400mg per 20ml vial

Tyenne brand- kept in MPUH

Reconstitution

Already in solution

Infusion fluids

Sodium chloride 0.9%

Methods of intravenous administration

Intermittent intravenous infusion (Administer using an electronically controlled infusion device)

- **Gloves, protective eyewear and a mask** should be worn by those handling this drug [ref 1,2]
- Withdraw from a 100ml bag of infusion fluid a volume equal to the volume of RoActemra concentrate required for the patient's dose
- Withdraw the required amount of RoActemra concentrate 0.4ml/kg (=8mg/kg) from the vial and place in the 100ml infusion bag. This should be a final volume of 100ml
- To mix the solution, gently invert the infusion bag to avoid foaming
- Administer over 1 hour

Dose in adults

If there has been a previous reaction to tocilizumab, consider pre-medication with analgesics,

antihistamines, and corticosteroids.[ref 2]

Rheumatoid arthritis

- Give 8mg/kg once every four weeks (maximum single dose = 800mg)
- Dose adjustments are recommended in patients with liver enzyme abnormalities, low absolute neutrophil count (ANC) and low platelet count. Refer to product information

Cytokine Release Syndrome (CRS)

- Tocilizumab can be given alone or in combination with corticosteroids
- Patients weighing 30kg or more
  - Give 8 mg/kg (to a max of 800mg)
  - If no clinical improvement in the signs and symptoms of CRS occurs after the first dose, up to 3 additional doses of tocilizumab may be administered
  - The interval between consecutive doses should be at least 8 hours

COVID-19 patients (those receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation)

- The decision to use this drug for this indication MUST be discussed with ID/Immunology/Critical Care
- Give 8 mg/kg (to a max of 800mg) as a single dose
- If clinical signs or symptoms worsen or do not improve after the first dose, one additional infusion of tocilizumab may be administered
- The interval between the two infusions should be at least eight hours
- Not recommended if
  - Liver enzymes: >10 x ULN
  - Absolute neutrophil count: <1 x 10^9/L
  - Platelet count: <50 x 10^3/uL

Monitoring

- Patients must be monitored closely for infections and screened for latent TB prior to starting therapy (does not apply to CRS indication)
- Screen for blood-borne viruses prior to initiation for Rheumatoid arthritis
- Monitor the patient for infusion-related reactions
- See under Further information regarding LFTs, FBC's and lipids

Further information

- For individuals whose body weight is more than 100kg, doses exceeding 800mg per infusion are not recommended
- Liver enzymes should be monitored every 4 to 8 weeks for the first 6 months of treatment, followed by every 12 weeks thereafter
- Caution is advised in patients with a low neutrophil or platelet count. Neutrophils and platelets should be monitored 4 to 8 weeks after start of therapy, and thereafter according to standard clinical practice.
- Elevations in lipid parameters may occur so these should be measured 4 to 8 weeks after initiation of therapy and managed accordingly

Storage

- Store between 2 and 8 ^{0}C, do not freeze
- Keep the container in the outer container (to protect from light)

References

SPC (RoActemra) downloaded from EMEA 17th December 2024

1: Information on file from Roche 14/4/16

2: Injectable Medicines guide, downloaded from Medusa 17th December 2024

Therapeutic classification

Monoclonal antibody