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, or see this link
- **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 80mg per 4ml vial

Tyenne 200mg per 10ml vial

Tyenne 400mg per 20ml vial

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]
- For doses 500mg or less
    - The dose volume can be added to a 100mL bag without needing to remove the equivalent volume beforehand [ref 2]
- For doses >500mg:
    - Withdraw from a 100ml bag of infusion fluid a volume equal to the volume of drug concentrate required for the patient's dose
    - Withdraw the required amount of drug 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