Tocilizumab Intravenous for Adults

Who can administer

May be administered by registered competent doctor or nurse/midwife

Important information

- For use in COVID-19 - see separate monograph
- Treatment with Tocilizumab should not be initiated in patients with active infections and treatment should be interrupted if a patient develops a serious infection until the infection is controlled
- Must have access to facilities for managing hypersensitivity reactions including **anaphylaxis -** See QPulse document: Infusion related patient reaction in nurse-led settings **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

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

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
  - 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
  - Doses exceeding 800 mg per infusion are not recommended in CRS patients

Monitoring

- Patients must be monitored closely for infections and screened for latent TB prior to starting therapy (does not apply to CRS indication)
- Monitor the patient for infusion-related reactions
- Patients may be pre-treated with antihistamines, hydrocortisone, and/or paracetamol to decrease the risk of 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
- Caution should be exercised in patients with hepatic impairment or disease
- The use of the drug has not been studied in patients with renal impairment, and so renal function should be monitored closely in these patients
- 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) 29th March 2021

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

2: Injectable Medicines guide, downloaded from Medusa 26/10/2021

Therapeutic classification

Monoclonal antibody