Tocilizumab for ADULT patients with severe COVID-19 with suspected hyperinflammation

Who can administer

May be administered by registered competent doctor or nurse/midwife

Important information

- See HSE website- for guidance on patient selection
- Tocilizumab is an **experimental medicine** in the context of management of severe COVID-19 disease **(unlicensed drug)**
- It should **only be considered** in patients who have **severe COVID-19 with suspected hyperinflammation** following consultant level multidisciplinary specialist input (critical care medicine, infection specialists, haematology)
- Must have access to facilities for managing hypersensitivity reactions including **anaphylaxis**
- 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)
- Withdraw from a 100ml bag of infusion fluid a volume equal to the volume of tocilizumab concentrate required for the patient's dose
- Withdraw the required amount of tocilizumab concentrate 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

COVID-19

- For patients greater than or equal to 30kg give 8mg per kg, to a maximum of 800mg per dose
- Dose rounding toÂ the nearest vial size is recommended
- Maximum single dose 800mg
- In exceptional circumstances, one additional dose may be considered no sooner than 8 hours after the initial dose if there has not been sufficient clinical improvement
- The decision to give a second dose must only be made following consultant level multi-disciplinary specialist input

Renal impairment (COVID-19 patients)

- No dose adjustment required
- In renal replacement therapies (APD,CAPD,HD/HDF/Highflux/CAV/VVHD)- unknown dialysability - use normal dose with caution

Hepatic impairment

- The safety and efficacy has not been studied in patients with hepatic impairment.Â No advice available from manufacturer re dose adjustments

Monitoring

COVID-19 specific monitoring (Serial monitoring of the following)

- Full Blood Count
- Ferritin
- C-Reactive Protein
- Fibrinogen
- D-dimers
- ALT and AST
- IL-6 (if available)
- Procalcitonin (if available; to help outrule bacterial superinfection)

Standard monitoring requirements

- 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 (this is part of the licensed recommendations for tocilizumab)- not known if required for this indication- clinical decision

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) 23rd August 2018

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

2: Email on file from Prof Mike O Dwyer and John Given 23rd March 2020

3: Interim recommendations for the use of Tocilizumab in the management of patients who have severe COVID-19 with suspected hyperinflammation, HSE 20th March 2020Â (Updated 31st March) - but see link now for updated guidance

Therapeutic classification

Monoclonal antibody