Eculizumab Intravenous for Adults

Who can administer

May be administered by registered competent doctor/nurse/midwife

Important information

Please contact pharmacy for guidance on approval process.

- See document attached for ordering and prescribing guidance

Eculizumab must NOT be initiated in patients:

- with unresolved Neisseria meningitidis infection
- who are not currently vaccinated against Neisseria meningitidis (unless they receive prophylactic treatment with appropriate antibiotics until 2 weeks after vaccination)

For up to date information on vaccination and prophylactic antibiotics - please see

- **CDC recommendations**
- **Vaccination recommendations** from manufacturer

Give **PATIENT INFORMATION BROCHURE and PATIENT SAFETY CARD.** Patient to **report fever, headache with fever or neck stiffness** (to out-rule meningitis)

As the product is **EXTREMELY EXPENSIVE,** it may be administered by **experienced personnel ONLY** (to ensure no wastage of product)

Available preparations

Soliris 300mg in 30ml vial (concentrate for infusion)

Reconstitution

Not required, already in solution

Infusion fluids

Sodium chloride 0.9% or glucose 5%

Methods of intravenous administration

Slow intravenous infusion

- Dilute with an equal volume of diluent as per table below (after dilution, the final concentration of the solution to be infused is 5mg/mL)
- Administer over 25 to 45 minutes
- The residual volume in the infusion line must be flushed through at the same rate to avoid significant underdosing

Dose and drug volume	Diluent volume	Total infusion volume after dilution	Method of preparation of infusion
300mg (30ml)	30ml	60ml	Remove 70ml from 100ml infusion bag and add 30ml drug solution
600mg (60ml)	60ml	120ml	Remove 190ml from 250ml infusion bag and add 60ml drug solution
900mg (90ml)	90ml	180ml	Remove 160ml from 250ml infusion bag and add 90ml drug solution
1200mg (120ml)	120ml	240ml	Remove 130ml from 250ml infusion bag and add 120ml drug solution

Dose in adults

Dose depends on indication

Atypical Haemolytic Uremic Syndrome (aHUS),refractory generalised Myasthenia Gravis and Neuromyelitis Optica Spectrum Disorder (NMOSD)	
Initial phase	900mg every week for the first 4 weeks, followed by
Maintenance phase	1200mg for the fifth week, followed by 1200mg every 14 +/- 2 days

Paroxysmal Nocturnal Haemoglobinuria (PNH)	
Initial phase	600mg every week for the first 4 weeks, followed by
Maintenance phase	900mg for the fifth week, followed by 900 mg every 14 +/-2 day**s**

Patient's with aHUS also requiring plasmapheresis, plasma exchange or fresh frozen plasma

Refer to the SPC as supplemental doses are required

Monitoring

- Monitor for **headache** (occurs in more than 10% of patients)
- aHUS patients should be monitored for signs and symptoms of **thrombotic microangiopathy (TMA) by measuring platelet counts, serum LDH and serum creatinine (see SPC** for further information)
- Patients should be monitored for **one hour following infusion.** If an adverse event occurs during administration the infusion may be slowed or stopped at the discretion of the physician. If the infusion is slowed, the **total infusion time may not exceed two hours** in adults and adolescents

Further information

Refer to SPC

Storage

Store in refrigerator (2 to 8 degrees C)

References

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Therapeutic classification

Selective immunosuppressants

Humanised monoclonal antibody