PNH National Service

LEEDS & LONDON

Eculizumab Administration Guidelines

Eculizumab is given weekly for the initial 5 weeks and then every 14 days from week 5 onwards. The dose is as follows:

Initial Phase

600 mg of Eculizumab via a 25 – 45 minute intravenous infusion every week for the first 4 weeks (weeks 1-4). This is followed by 900 mg of eculizumab for the fifth week of the initial phase.

Maintenance Phase

900 mg of Eculizumab administered via a 25 – 45 minute intravenous infusion every 14 days starting from week seven.

Once in the maintenance phase, the day of the infusion can be moved by up to 2 days, but this must be agreed upon by the prescribing centre.

Higher Doses

Some individuals require higher doses of Eculizumab. If this is required, it will be organised by the prescribing centre.

Important issues regarding Eculizumab administration

- Eculizumab should only be administered by a healthcare professional.
- Observations should be done prior to the infusion.
- If the patient has a temperature of 38°C the PNH team should be contacted and the Eculizumab infusion should still be administered.
- Venous access should be secured before reconstituting the drug.
- Adherence to the aseptic technique should be followed at all times.
- It is given by an intravenous infusion over 25-45 min via a normal giving set, free flow gravity or pump.
- Patients should be monitored for signs of hypersensitivity during the infusion and one hour following the infusion.
- If an adverse event occurs during the administration of Eculizumab, the infusion must be stopped and the referring centre contacted for advice. If the infusion is slowed or stopped, the total infusion time may not exceed two hours.
- Any adverse events must be documented and reported to the prescribing centre.

Side Effects

The most common side effects reported are headache, nasopharygitis, nausea and pyrexia reported in 5% of patients.

Storage

- Store in a refridgerator between 2-8°C.
- Do not freeze.
- Store in original package to protect from light.
- If there is any doubt that the drug has been stored incorrectly, contact the referring centre immediately.
- After dilution the drug should be used immediately.

Preparing the Infusion

Adhere to the aseptic technique at all times. If any problems occur during reconstitution, contact the PNH team before destroying the infusion (See preparing the infusion below):

600 mg

Using a 100mls 0.9% sodium chloride bag, withdraw (using a 50ml syringe) 40mls from the bag. Draw up a total of 60mls of Eculizumab (600 mg) from the vials (2 vials) and add to the remaining 60mls of 0.9% sodium chloride. This gives a total volume of 120mls in the bag. Gently agitate the bag, checking for particles. The solution should be clear and colourless.

900 mg

Using a 250mls 0.9% sodium chloride bag, withdraw (using 50mls syringes) 160mls from the bag. Draw up a total of 90mls of Eculizumab (900 mg) from the vials (3 vials) and add to the remaining 90mls of 0.9 % sodium chloride. This gives a total volume of 180mls in the bag. Gently agitate the bag, checking for particles. The solution should be clear and colourless.

1200 mg

Using a 250mls 0.9% sodium chloride bag, withdraw (using 50mls syringes) 130mls from the bag. Draw up a total of 120mls of Eculizumab (1200 mg) from the vials (4 vials) and add to the remaining 120mls of 0.9% sodium chloride. This gives a total volume of 240mls in the bag. Gently agitate the bag, checking for particles. The solution should be clear and colourless.