PNH National Service

LEEDS & LONDON

Ravulizumab Administration Guidelines

Ravulizumab is a monoclonal antibody treatment given for PNH (Paroxysmal Nocturnal Haemoglobinuria). Ravulizumab is given two weekly for the initial 2 doses and then every 8 weeks. The dose is as follows:

Dose

The dosing regimen consists of an initial phase dose on Day 1 followed by a maintenance phase on Day 15.

Initial phase: Loading dose administration reference table

Body Weight Range (kg)*	Loading Dose (mg)	Total volume when diluted in sodium chloride 0.9% (50 mg/ml)	Infusion Duration
≥ 40 to < 60	2,400	48ml	1 Hour
≥ 60 to < 100	2,700	54ml	1 Hour
≥ 100	3,000	60ml	1 Hour

* Body weight at time of treatment.

Ravulizumab should only be diluted using sodium chloride 9 mg/mL (0.9 %) solution for injection. **The first maintenance dose is administered on Day 15 after loading dose.**

Followed Maintenance dose administration reference table

Body Weight Range (kg)*	Maintenance Dose (mg)	Frequency	Total volume when diluted in sodium chloride 0.9% (50 mg/ml)	Infusion Duration
≥ 40 to < 60	3,000	Every 8 weeks	60ml	1 Hour
≥ 60 to < 100	3,300	Every 8 weeks	66ml	1 Hour
≥ 100	3,600	Every 8 weeks	72ml	1 Hour

* Body weight at time of treatment.

Ravulizumab should only be diluted using sodium chloride 9 mg/mL (0.9 %) solution for injection.

The maintenance phase is administered every 8 weeks. There is a +/- 7 days that the dose can be given (but not the first maintenance dose this is at day 15 after the first dose) a date change must be agreed upon by the prescribing centre.

Important issues regarding Ravulizumab administration

- Ravulizumab should be only administered by a healthcare professional.
- Observations should be done prior to the infusion, during and after if the patient has a temperature of >38oC the PNH team should be contacted immediately on 0113 2068625 or out of hours 07920535918. Or the prescribing team if outside England.
- Venous access should be secured before reconstituting the drug.
- Adherence to aseptic technique should be followed at all times
- Only be given by an intravenous infusion. At the Leeds PNH Service, all doses are given over one hour.
- This medicinal product must be administered through a 0.2 µm filter and should not be administered as an intravenous push or bolus injection. Ideally via an infusion pump.
- Sodium chloride 0.9% flush before and after infusion should be administered.
- Patients should be monitored for signs of hypersensitivity during the infusion and one hour following infusion.
- If an adverse event occurs during the administration of Ravulizumab, the infusion must be stopped and the referring centre must be contacted for advice.
- Any adverse events must be documented and reported to the prescribing centre.

Side Effects

The most common side effects reported are headache, nausea and loose stools.

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.

1. The number of vials to be diluted is determined based on the individual patient's weight and the prescribed dose

2. Prior to dilution, the solution in the vials should be visually inspected; the solution should be free of any particulate matter or precipitation. Do not use if there is evidence of particulate matter or precipitation.

3. The calculated volume of the medicinal product is withdrawn from the appropriate number of vials and diluted in an infusion bag using sodium chloride 0.9 % solution for injection as diluent. The product should be mixed gently. It should not be shaken.

4. After dilution, the final concentration of the solution to be infused is 50 mg/mL.

5. The prepared solution should be administered immediately following preparation unless it is stored at 2 °C-8 °C. If stored at 2 °C - 8 °C, allow the diluted solution to warm to room temperature prior to administration. Do not administer as an intravenous push or bolus injection. Infusion must be administered through a 0.2 µm filter.

6. If the medicinal product is not used immediately after dilution, storage times must not exceed 24 hours at 2 °C – 8 °C or 6 hours at room temperature taking into account the expected infusion time.

If any problems occur during reconstitution contact the PNH team before destroying the infusion.

Please do not hesitate to contact the PNH team / referring centre with any queries.