Ocrelizumab Intravenous Infusion for Adults

Who can administer

May be administered by registered competent doctor or nurse/midwife

Important information

- **Premedication**: **an anti-pyretic and an antihistamine** should always be administered 30 to 60 minutes prior to each infusion of ocrelizumab
- **Premedication with intravenous methylprednisolone** 100mg (local protocols use 80mg doses)(ref 1)(ref 2) should be completed 30 minutes prior to each ocrelizumab infusion
- **Infusion related reactions** (IRR) can be a concern with this drug- ensure adrenaline, corticosteroids and antihistamine are available for immediate administration if needed
- **Hepatitis B virus** (HBV) screening should be performed in all patients prior to treatment with ocrelizumab. Patients with active HBV should not commence treatment
- Ocrelizumab **should NOT be administered** to patients with an **active, severe infection** (eg tuberculosis, sepsis and opportunistic infections) or severely immunocompromised patients
- **Contraindicated** in patients with **known active malignancies**
- Monitor for signs and symptoms of **PML**
- In order to improve the traceability of biological medicinal products, the **name and the batch number of the administered product should** be clearly **recorded in the patients file**
- See attached prescription sheets for OPD

Available preparations

Ocrevus 300mg in 10ml vial

Reconstitution

Already in solution

Dilute further prior to administration

Infusion fluids

Sodium Chloride 0.9%

Methods of intravenous administration

Intermittent intravenous infusion (using an electronically controlled infusion device)

Dilute as follows before administration to produce a final drug concentration of approximately

1.2mg/ml.

Preparation of initial 300mg dose (Infusions 1 and 2):

- Add 300mg of ocrelizumab into a 250ml infusion bag of sodium chloride 0.9%

Preparation of subsequent doses (600mg)

- Add 600mg of ocrelizumab into a 500ml infusion bag of sodium chloride 0.9%

Administration of infusion

- Give the diluted solution using an infusion set with a 0.2 or 0.22 micron in-line filter
- The content of the infusion bag should be at room temperature prior to the start of the infusion
- **First and second infusions of 300mg** in 250ml
    - Each infusion should be **given over approximately 2.5 hours**
    - The recommended initial rate for infusion is 30ml per hour for first 30 minutes
    - It can be increased in 30ml per hour increments every 30 minutes to a maximum of 180ml per hour
- **Subsequent infusions of 600mg** in 500mls
    - **Option 1**
        - Each infusion should be **given over approximately 3.5 hours**
        - Infuse at an initial rate of 40ml per hour for the first 30 minutes
        - Increase by 40ml per hour increments every 30 minutes to a maximum of 200ml per hour
    - **Option 2 (if no infusion related reactions with any previous ocrelizumab infusion)**
        - Each infusion should be **given over approximately 2 hours**
        - Infuse at an initial rate of 100ml per hour for the first 15 minutes
        - increase rate to 200mL per hour for the next 15 minutes
        - then increase to 250mL per hour for the next 30 minutes
        - then increase to 300mL per hour for the remaining 60 minutes

Dose in adults

Relapsing multiple sclerosis (RMS) and primary progressive multiple sclerosis (PPMS)

- **Initial dose-** The initial 600mg dose is **administered as two separate 300mg** IV infusions; a 300mg infusion administered on day 1 and followed 2 weeks later by a second 300mg infusion
- **Subsequent doses**-subsequent doses are administered as a single 600mg infusion every 6 months. The first subsequent dose should be administered 6 months after the first initial dose

Monitoring

- Please also consult Medication Protocol: Management of Infusion Related patient Reactions in nurse-led infusion setting in GUH. QPulse CLN-NM-0118
- All patients must be monitored **during the infusion and for at least one hour** after the infusion
- During the infusion any patients who experience **severe pulmonary symptoms such as bronchospasm or asthma** exacerbation should have the infusion **stopped immediately and permanently** and receive symptomatic treatment

- For **mild to moderate IRR** (such as headache) the infusion rate should be **reduced to half for at least 30 minutes**, if tolerated the rate can be increased back to initial infusion rate
- Closely monitor for **cytokine release syndrome** (can occur within 24 hours of infusion). Patients who develop severe reactions, especially dyspnoea, or a complex of flushing, fever and throat pain symptoms should receive symptomatic treatment. In all patients, the infusion should not be restarted until complete resolution of all symptoms. At this time, the infusion can be resumed at not more than half the rate at the time of IRR onset.In the case of life-threatening acute hypersensitivity, acute respiratory or similar IRR, the infusion should be stopped immediately and aggressive symptomatic treatment provided. Ocrelizumab should be permanently discontinued.
- For full information on monitoring requirements : see SPC

Further information

- **Hypotension** may occur as a symptom of IRR. Some consideration should be given to **withholding antihypertensive** treatments for 12 hours prior to and throughout each ocrelizumab infusion
- Patients who require **vaccination** should complete their immunisation at least 6 weeks prior to initiation of ocrelizumab

Storage

- Store between 2 and 8^{0}C
- Do not freeze
- Keep in outer carton (to protect from light)

References

SPC Ocrevus September 2022

1: Ocrelizumab (Ocrevus) Prescription sheet Neurology Initial 300mg dose(s)

2: Ocrelizumab(Ocrevus) Prescription sheet Neurology Subsequent 600mg

Therapeutic classification

Monoclonal antibody