Natalizumab Intravenous for Adults

Who can administer

May be administered by registered competent doctor or nurse/midwife

Important information

- Natalizumab has been associated with an **increased risk of PML**; the risk increases with treatment duration, especially beyond two years
- Must be initiated and supervised by **consultant neurologist**
- Must have access to facilities for managing hypersensitivity reactions including **anaphylaxis.** See QPulse document: Infusion related Patient reaction in nurse-led setting **CLN-NM-0118**
- See section on monitoring requirements
- **Each patient must be given a special alert card (and patient information leaflet) that summarises the key safety information about natalizumab -** see Pharmacy Information below
- In order to improve the traceability of biological medicinal products, **the name and batch number of the administered product should be clearly recorded**

Available preparations

Tysabri 300mg per 15ml vial

Reconstitution

Already in solution

Dilute further prior to administration

Infusion fluids

Sodium chloride 0.9%

Methods of intravenous administration

Intermittent intravenous infusion (administer using an electronically controlled infusion device)

- Add 300mg (15ml) to 100ml infusion fluid
- **Gently invert** solution to mix completely (do not shake)
- Infuse only if the infusion is FREE FROM particles and discolouration
- Administer **over 60 minutes** (rate of infusion is approximately 2ml/minute)

Dose in adults

- Give 300mg by intravenous infusion, repeated every 4 weeks

Renal or hepatic dysfunction

- No studies conducted
- The mechanism for elimination and results from population pharmacokinetics suggest that dose

adjustment would not be necessary in patients with renal or hepatic impairment

Monitoring

- **Monitor the patient** for signs and symptoms of **hypersensitivity** reaction during and for at least one hour **after** the infusion has finished.
- **MRI** is recommended annually
- Regular assessment for **neurological dysfunction** is recommended (during treatment and for approximately six months after discontinuation), in particular symptoms suggestive of PML e.g. cognitive or psychiatric symptoms.
- Monitor LFTs
- **Opportunistic infections** have been reported in patients receiving natalizumab
- **Acute retinal necrosis** has been reported- if decreased visual acuity, redness or painful eye reported, refer for retinal screening

Further information

- Disease exacerbations or **infusion related events** may indicate the **development of antibodies against natalizumab**. In these cases the presence of antibodies should be evaluated and if these remain positive in a confirmatory test after at least 6 weeks, treatment should be discontinued.; See SPC for further information

Pharmacy information

- A Patient pack (including a patient alert card) is available, contact 1800 812719 or email medinfouki@biogen.com- Ensure patient has been given this pack when treatment is initiated
- There is a OPD patient prescription sheet available for use in clinic (in-patients: may be prescribed on regular prescription chart)

Storage

- Store between 2 and 8^{0}C
- Do not freeze

References

SPC 09/2024

Therapeutic classification

Immunomodulatory drug