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
- Recent MRI (within 3 months) prior to initiation
- **Each patient must be given a special alert card (and patient information leaflet) that summarises the key safety information about natalizumab**
- In order to improve the traceability of biological medicinal products, **the name and batch number of the administered product should be clearly recorded**
- See OPD prescription

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, however a dosage reduction MAY not be necessary. There are post-marketing reports of liver injury

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.
- Consider vigilant monitoring of **liver function tests** given the recent alert published by the FDA
- **Consider discontinuing the drug after 6 months** if no benefit is evident
- **Reassess** the risk:benefit before or at **2 years**
- **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

- Natalizumab is indicated only as single agent disease modifying therapy
- Natalizumab is indicated only for patients with high disease activity despite adequate treatment with at least one disease modifying therapy OR in patients with rapidly evolving **severe** relapsing remitting multiple sclerosis
- Patients may switch directly from beta interferon or glatiramer acetate to natalizumab provided there are no signs of adverse effects such as neutropenia
- The drug may remain **active for approximately 12 weeks after discontinuation**, therefore careful consideration should be given before reinstating other therapies within this time period (short courses of steroids used during clinical trials were **not** associated with increased infections)
- Natalizumab is not recommended in adults over 65 years
- 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, as persistent antibodies are associated with a substantial decrease in efficacy of TYSABRI and an increased incidence of hypersensitivity reactions. **Since patients who have received an initial short exposure to TYSABRI and then had an extended period without treatment are at a higher risk of developing anti-natalizumab antibodies** and/or hypersensitivity upon re-dosing, the presence of antibodies should be evaluated and if these remain positive in a confirmatory test after at least 6 weeks, the patient should not receive further treatment with the drug

Pharmacy information

- Patient addressograph details are provided and that the patient has been given a special alert card (as indicated on the prescription)
- Natalizumab should be prescribed on the"Natalizumab Treatment Sheet" only
- The drug is issued on a named-patient basis
- A Patient pack (including a patient alert card) is available, contact 1800 812719 or email medinfouki@biogen.com

Storage

- Concentrate - store between 2 and 8^{0}C

References

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Therapeutic classification

Immunomodulatory drug