**natalizumab** (na-ta-li-zoo-mab)

**Therapeutic:** anti-multiple sclerosis agents
**Pharmacologic:** monoclonal antibodies

**Drug Class:** Therapeutic: anti-multiple sclerosis agents

**Pregnancy Category:** C

**Indications**

- To reduce the frequency of exacerbations of relapsing multiple sclerosis.
- Inducing and maintaining remission in moderately to severely active Crohn’s disease in patients who have been unresponsive to conventional therapies, including tumor necrosis factor inhibitors.

**Action**

Binds to integrin receptors on non-neutrophil leukocytes which may alter adhesion and migration characteristics involved in the crossing of activated inflammatory cells into the CNS. Therapeutic Effects:

- Fewer exacerbations of relapsing multiple sclerosis.

**Pharmacokinetics**

- **Absorption:** IV administration results in complete bioavailability.
- **Distribution:** Unknown.
- **Metabolism and Excretion:** Unknown.
- **Half-life:** 7–15 days.

**TIME/ACTION PROFILE**

<table>
<thead>
<tr>
<th>ROUTE</th>
<th>ONSET</th>
<th>PEAK</th>
<th>DURATION</th>
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<tbody>
<tr>
<td>IV</td>
<td>unknown</td>
<td>unknown</td>
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</table>

**Contraindications/Precautions**

Contraindicated in: Hypersensitivity, Concurrent use of immunosuppressants or tumor necrosis factor inhibitors, History of progressive multifocal leukoencephalopathy (PML), Pediculosis

**Use Cautiously in:** Anti-JC virus (JCV) positive; OB: Use only if clearly needed.

**Adverse Reactions/Side Effects**

- **CNS:** depression, fatigue.
- **GI:** HEPATOTOXICITY, cholelithiasis.
- **Derm:** melanoma.
- **Misc:** allergic reactions including ANAPHYLAXIS, infections, PML, infusion-related reactions.

**Interactions**

**Drug-Drug:** Risk of infection with immunosuppressants (avoid concurrent use).

**Route/Dosage**

**Multiple Sclerosis**

- **IV (Adults):** 300 mg every 4 wk.

**Crohn's Disease**

- **IV (Adults):** 300 mg every 4 wk; if no response after 12 wk, or if patient cannot be tapered off corticosteroid therapy after 6 mo, discontinue therapy.

**NURSING IMPLICATIONS**

**Assessment**

- Observe patient during infusion and for 1 hr after infusion is completed.
- Assess for signs of hypersensitivity reactions (urticaria, dizziness, fever, rash, rigors, pruritus, nausea, flushing, hypotension, dyspnea, chest pain, anaphylaxis), especially during first 2 hrs of infusion. If symptoms occur, discontinue natalizumab and treat symptoms.
- Assess for new signs or symptoms suggestive of PML, an opportunistic infection of the brain caused by the JC virus, leading to death or severe disability; withhold dose and notify health care professional promptly. Monitor during therapy and for at least 6 months following discontinuation. PML symptoms may begin gradually but usually worsen rapidly. Symptoms vary depending on which part of the brain is infected (mental function declines rapidly and progressively, causing dementia; speaking becomes increasingly difficult; partial blindness; difficulty walking; rarely, headaches and seizures occur). Diagnosis is usually made via gadolinium-enhanced MRI and CSF analysis. Risk of PML increases with the number of infusions. Withhold natalizumab at diagnosis of PML.

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● Obtain an MRI of the brain prior to initiating therapy to help in differentiating symptoms of MS with those of PML.

● MS: Assess frequency of exacerbations of symptoms of multiple sclerosis periodically during therapy.

● Crohn’s Disease: Assess abdominal pain and frequency, quantity, and consistency of stools at beginning and during therapy.

● Lab Test Considerations: May cause lymphopenia, mononucelosis, eosinophilia, basophilia, and nucleated RBCs. These persist during therapy but usually return to baseline within 16 weeks after last dose. Neutropenia is not usually seen.

● May cause hepatotoxicity. Monitor for serum hepatic enzymes and total bilirubin may occur within 6 days after the first dose or for the first time after multiple doses. Discontinue if jaundice or other evidence of hepatotoxicity occurs.

● Monitor serum JCV antibodies periodically during therapy. Patients with a negative antibody should be retested periodically during therapy due to potential for false-negative or false-positive results or cause infection.

Potential Nursing Diagnoses
Deficient knowledge, related to medication regimen (Patient/Family Teaching)

Implementation
IV Administration

● Intermittent Infusion: Diluted: Dilute 300 mg in 100 mL of 0.9% NaCl. Invert to mix solution; do not shake. Do not mix with other infusions. Solution is colorless and clear to slightly opalescent. Do not administer solutions that are discolored or contain particulate matter. Administer immediately after dilution or refrigerate and use within 8 hrs. Concentration: 2.6 mg/mL. Rate: Infuse over 1 hr. Do not use filtration devices. Do not administer as IV push or bolus injection.

Patient/Family Teaching

● Inform patient of purpose of medication. Patients must visit their health care professional/prescriber 3 and 6 months after first infusion and every 6 months thereafter for follow-up exams.

● Instruct patient to read the Medication Guide before starting the infusion. Single use vials is available only through a special restricted distribution program called the TOUCH™ Prescribing Program, MS-TOUCH for multiple sclerosis and CD-TOUCH for Crohn’s Disease, and must be administered only to patients enrolled in the program.

● Instruct patient to report symptoms of PML (progressive weakness on one side of the body or clumsiness of limbs; disturbance of vision; changes in thinking, memory, and orientation leading to confusion and personality changes), hypersensitivity reactions, hepatotoxicity (yellowing of the skin and eyes, unusual darkening of the urine, nausea, feeling tired or weak, vomiting), or worsening of symptoms (new or sudden change in your thinking, eyesight, balance, or strength) that persist over several days to health care professional immediately.

● Advise patient to notify health care professional of all Rx or OTC medications, vitamins, or herbal products being taken and to consult with health care professional before taking other medications.

● Advise patient to notify health care professional about treatment with natalizumab.

● Advise patient to notify health care professional if pregnancy is planned or suspected or if breast feeding.

Evaluation/Desired Outcomes

● Decrease in frequency of clinical exacerbations in patients with multiple sclerosis.

● Decrease in signs and symptoms of Crohn’s disease.

● Patients must be evaluated at 3 mo and 6 mo after first infusion and every 6 mo thereafter to determine effectiveness.

Why was this drug prescribed for your patient?