

### Tysabri® (natalizumab) – New warning

- On August 16, 2017, the FDA approved a new warning to the [Tysabri \(natalizumab\)](#) drug label regarding acute retinal necrosis (ARN).
- Tysabri is indicated as monotherapy for the treatment of patients with relapsing forms of multiple sclerosis and for inducing and maintaining clinical response and remission in adults with moderately to severely active Crohn's disease.
- ARN is a fulminant viral infection of the retina caused by the family of herpes viruses (eg, varicella zoster, herpes simplex virus). A higher risk of ARN has been observed in patients being administered Tysabri.
  - Patients presenting with eye symptoms, including decreased visual acuity, redness, or eye pain, should be referred for retinal screening for ARN.
  - Some ARN cases occurred in patients with central nervous system herpes infections (eg, herpes meningitis or encephalitis). Serious cases of ARN led to blindness of one or both eyes in some patients.
  - Following clinical diagnosis of ARN, healthcare providers should consider discontinuation of Tysabri. The treatment reported in ARN cases included anti-viral therapy and, in some cases, surgery.