

Actimmune® (interferon gamma-1b)



When requesting Actimmune® (interferon gamma-1b), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications or approved compendial uses and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-approved indications

- To reduce the frequency and severity of serious infections associated with chronic granulomatous disease¹
- To delay time to disease progression in individuals with severe, malignant osteopetrosis¹

Approved Off-label Compendial uses²

- None*

*Oncology-related off-label uses are addressed in the Medical Oncology program.

Coverage Guidelines

For all approved indications, the individual does **not** have the following contraindication or exclusion to therapy:

- Known hypersensitivity to interferon gamma, *E.coli* derived products, or any component of the product¹

The individual must have **one** of the following diagnoses for approval:

- Chronic granulomatous disease¹
- Severe, malignant osteopetrosis¹

Approval duration: 12 months

Additional Information for Prescribers¹

- Pre-existing cardiac conditions may be exacerbated by Actimmune® (interferon gamma-1b).
- Reduce dose or discontinue Actimmune® (interferon gamma-1b) if decreased mental status, gait disturbance, or dizziness occur. Monitor patients with seizure disorders or compromised CNS function when administering Actimmune®.
- Monitor for neutropenia and thrombocytopenia particularly when administering Actimmune® (interferon gamma-1b) in combination with other potentially myelosuppressive agents.
- Reduce dose or discontinue Actimmune® (interferon gamma-1b) to reverse severe elevations of aspartate transaminase (AST) and/or alanine transaminase (ALT); monitor liver function monthly in individuals less than 1 year old.
- If serious hypersensitivity reactions occur, discontinue Actimmune® (interferon gamma-1b) and institute appropriate medical therapy.
- Monitor renal function regularly when administering Actimmune® (interferon gamma-1b) to individuals with severe renal insufficiency.

References

1. Actimmune® solution for injection (interferon gamma-1b) [prescribing information]. Roswell, GA: HZNP USA; July 2016. http://www.actimmune.com/pdf/ACTIMMUNE_PI_Effective_US%207-16.pdf. Accessed February 6, 2017.
2. Klasco RK (Ed): DRUGDEX® system. Thomson Micromedex, Greenwood Village, CO. Accessed February 6, 2017. <https://www.micromedexsolutions.com>.
3. Leiding JW, Holland SM. Chronic Granulomatous disease. NCBI Bookshelf; February 11, 2017. <https://www.ncbi.nlm.nih.gov/books/NBK99496/>. Accessed February 6, 2017.
4. Stark Z, Savarirayan R. Osteopetrosis. *Orphanet J Rare Dis*. 2009;4:5. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2654865/> Accessed February 6, 2016.
5. Wilson CJ, Vellodi A. Personal practice: Autosomal recessive osteopetrosis: Diagnosis, management, and outcome. *Arch Dis Child* 2000;83:449-452. <http://adc.bmj.com/content/83/5/449.full.pdf+html>. Accessed February 6, 2017.