



Company: Sobi, Inc.

Product Trade Name: Gamifant® (emapalumab-lzsg)

Generic Name: emapalumab-lzsg

Indication: Gamifant is an interferon gamma (IFN γ)-blocking antibody indicated for the treatment of adult and pediatric (newborn and older) patients with primary hemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent, or progressive disease or intolerance with conventional HLH therapy.¹

Product Information

How supplied¹	Gamifant Injection is a sterile, clear to slightly opalescent, colorless to slightly yellow solution	
Packaging	Gamifant is supplied in a single-use vial in 2 different vial sizes	
NDC numbers¹	72171-501-01	10 mg/2 mL (5 mg/mL) single-use vial
	72171-505-01	50 mg/10 mL (5 mg/mL) single-use vial
HCPCS code²	J Code	J9210: Injection, emapalumab-lzsg, 1 mg
ICD-10 code³	D76.1: Hemophagocytic lymphohistiocytosis	
CPT code^{4,*}	96365: Therapeutic, Prophylactic, and Diagnostic Injections and Infusions	
EAPG code⁵	780: Other hematologic diagnoses	

CPT=Current Procedural Terminology; EAPG=Enhanced Ambulatory Patient Group; HCPCS=Healthcare Common Procedure Coding System; ICD-10=International Classification of Diseases, Tenth Revision; NDC=National Drug Code.

*Additional codes may be needed for procedures required to properly administer Gamifant.

Dosage and Administration: Administer Gamifant until hematopoietic stem cell transplantation (HSCT) is performed or unacceptable toxicity. Discontinue Gamifant when a patient no longer requires therapy for the treatment of HLH.¹

Storage Requirements: Store Gamifant in a refrigerator at 2°C to 8°C (36°F to 46°F) in original carton to protect from light. Do not freeze or shake. This product contains no preservative.¹

Important Safety Information

Before initiating Gamifant, patients should be evaluated for infection, including latent tuberculosis (TB). Prophylaxis for TB should be administered to patients who are at risk for TB or known to have positive purified protein derivative (PPD) test result or positive IFN γ release assay.

Please see additional Important Safety Information on the reverse side and accompanying full Prescribing Information.





Indication and Usage

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During Gamifant treatment, patients should be monitored for TB, adenovirus, Epstein-Barr virus (EBV), and cytomegalovirus (CMV) every 2 weeks and as clinically indicated.

Patients should be administered prophylaxis for herpes zoster, *Pneumocystis jirovecii*, and fungal infections prior to Gamifant administration.

Do not administer live or live attenuated vaccines to patients receiving Gamifant and for at least 4 weeks after the last dose of Gamifant. The safety of immunization with live vaccines during or following Gamifant therapy has not been studied.

Infusion-Related Reactions

Infusion-related reactions, including drug eruption, pyrexia, rash, erythema, and hyperhidrosis, were reported with Gamifant treatment in 27% of patients. In one-third of these patients, the infusion-related reaction occurred during the first infusion.

Adverse Reactions

In the pivotal trial, the most commonly reported adverse reactions ($\geq 10\%$) for Gamifant included infection (56%), hypertension (41%), infusion-related reactions (27%), pyrexia (24%), hypokalemia (15%), constipation (15%), rash (12%), abdominal pain (12%), CMV infection (12%), diarrhea (12%), lymphocytosis (12%), cough (12%), irritability (12%), tachycardia (12%), and tachypnea (12%).

Additional selected adverse reactions (all grades) that were reported in less than 10% of patients treated with Gamifant included vomiting, acute kidney injury, asthenia, bradycardia, dyspnea, gastro-intestinal hemorrhage, epistaxis, and peripheral edema.

Please see the full Prescribing Information for Gamifant.

References: 1. Gamifant [prescribing information]. Stockholm, Sweden: Swedish Orphan Biovitrum AB; 2018. 2. Centers for Medicare & Medicaid Services. HCPCS Quarterly Update. <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Downloads/Other-Codes-2019-July-Revised.zip>. Accessed September 11, 2019. 3. ICD-10 Code for hemophagocytic lymphohistiocytosis D76.1. AAPC Coder website. <https://coder.aapc.com/icd-10-codes/D76.1>. Accessed September 11, 2019. 4. CPT 96365, Under therapeutic, prophylactic, and diagnostic injections and infusions (excludes chemotherapy and other highly complex drug or highly complex biologic agent administration). AAPC Coder website. <https://coder.aapc.com/cpt-codes/96365>. Accessed September 11, 2019. 5. 3M Health Information Systems. EAPG listing: effective October 1, 2018. https://dhcf.dc.gov/sites/default/files/dc/sites/dhcf/page_content/attachments/DC%20EAPG%20Relative%20Weights%20Eff%2010-1-18%20DCO18023.pdf. Published August 23, 2018. Accessed September 11, 2019.



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