gamifant®
emapalumab-lzsg

Company: Sobi, Inc.

Product Trade Name: Gamifant® (emapalumab-lzsg)

Generic Name: emapalumab-lzsg

Indication: Gamifant is an interferon gamma (IFNγ)-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 supplied[1]	Gamifant Injection is a sterile, clear to slightly opalescent, colorless to slightly yellow solution	
Packaging	Gamifant is supplied in a single-use vial in 3 different vial sizes	
NDC numbers[1]	**72171-501-01** **72171-505-01** **66658-510-01**	10 mg/2 mL (5 mg/mL) single-use vial 50 mg/10 mL (5 mg/mL) single-use vial 100 mg/20 mL (5 mg/mL) single-use vial
HCPCS code[2]	**J Code**	**J9210:** Injection, emapalumab-lzsg, 1 mg
ICD-10 code[3]	**D76.1:** Hemophagocytic lymphohistiocytosis	
CPT code[4,*]	**96365:** Therapeutic, Prophylactic, and Diagnostic Injections and Infusions	
EAPG code[5]	**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 IFNγ release assay.

Please see additional Important Safety Information on the next page and full Prescribing Information for Gamifant.

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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 (≥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]. Waltham, MA: Sobi Inc; 2020. **2.** Centers for Medicare & Medicaid Services. Alpha-Numeric HCPCS 2020. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2020-Alpha-Numeric-HCPCS-File. Accessed July 15, 2020. **3.** ICD-10 Code for hemophagocytic lymphohistiocytosis D76.1. AAPC Coder website. https://coder.aapc.com/icd-10-codes/D76.1. Accessed July 15, 2020. **4.** American Medical Association. *CPT® 2020 Professional Edition*. Chicago, IL: American Medical Association; 2020. **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 July 15, 2020.

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