gamifant®
emapalumab-lzsg

Company: Sobi, Inc.

Product Trade Name: Gamifant®

Generic Name: emapalumab-lzsg

Indications: Gamifant is indicated for the treatment of[1]:

- adult and pediatric (newborn and older) patients with primary hemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent or progressive disease or intolerance with conventional HLH therapy.
- adult and pediatric (newborn and older) patients with HLH/macrophage activation syndrome (MAS) in known or suspected Still's disease, including systemic Juvenile Idiopathic Arthritis (sJIA), with an inadequate response or intolerance to glucocorticoids, or with recurrent MAS.

Product Information

How supplied[1]	Gamifant Injection is a sterile, clear to slightly opalescent, colorless to slightly yellow solution	
Packaging[1]	Gamifant is supplied in a single-use vial in 3 different vial sizes	
NDC numbers[1]	66658-501-01 66658-505-01 66658-510-01	Containing one 10 mg/2 mL (5 mg/mL) single-dose vial Containing one 50 mg/10 mL (5 mg/mL) single-dose vial Containing one 100 mg/20 mL (5 mg/mL) single-dose vial
HCPCS code[2]	J Code	J9210: Injection, emapalumab-lzsg, 1 mg
***ICD-10-CM* codes**[3]	D76.1: Hemophagocytic lymphohistiocytosis D76.2: Hemophagocytic syndrome, infection-associated M06.1: Adult-onset Still's disease M08.09: Unspecified juvenile rheumatoid arthritis, multiple sites M08.20: Juvenile rheumatoid arthritis with systemic onset, unspecified site	
***ICD-10-PCS* codes**[4,5]	XW033MA: Introduction of emapalumab-lzsg anti-IFNγ monoclonal antibody into peripheral vein, percutaneous approach, new technology group 10 XW043MA: Introduction of emapalumab-lzsg anti-IFNγ monoclonal antibody into central vein, percutaneous approach, new technology group 10	
CPT® code[6,*]	96365: Therapeutic, prophylactic, and diagnostic injections and infusions	
EAPG code[7]	780: Other hematological diagnoses	

CPT®=Current Procedural Terminology®; EAPG=Enhanced Ambulatory Patient Group; HCPCS=Healthcare Common Procedure Coding System; *ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification*; *ICD-10-PCS=International Classification of Diseases, Tenth Revision, Procedure Coding System;* IFNγ=interferon gamma; NDC=National Drug Code.
*Additional codes may be needed for procedures required to properly administer Gamifant.

IMPORTANT SAFETY INFORMATION

Infections

Gamifant may increase the risk of fatal and serious infections with pathogens including mycobacteria, herpes zoster virus, and histoplasma capsulatum. Do not administer Gamifant in patients with these infections until appropriate treatment has been initiated.

Please see additional Important Safety Information throughout and full Prescribing Information for Gamifant.

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Dosage and Administration of Gamifant® (emapalumab-lzsg)

In primary HLH, Gamifant is administered by central or peripheral IV infusion over 1 hour twice per week (every 3 to 4 days) until hematopoietic stem cell transplantation (HSCT) is performed or unacceptable toxicity. The recommended starting dose is 1 mg/kg.[1]

1 mg/kg
intravenously infused over 1 hour every 3-4 days

Until HSCT

DAY 1+

In HLH/MAS, Gamifant is administered by central or peripheral IV infusion over 1 hour. The recommended initial dose of Gamifant is 6 mg/kg. Following this dose, Gamifant should be administered as follows[1]:

+ Continue administering Gamifant twice per week until HLH/MAS remission is achieved based on healthcare provider assessment.

Refer to Gamifant Prescribing Information for dose modifications in primary HLH and HLH/MAS.

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

IV=intravenous.

References: 1. Gamifant (emapalumab-lzsg) prescribing information. Stockholm, Sweden: Sobi, Inc. 2025. **2.** Healthcare Common Procedure Coding System (HCPCS) application summaries for drugs, biologicals and radiopharmaceuticals. Centers for Medicare & Medicaid Services (CMS). Published May 14, 2019. Accessed May 16, 2025. https://www.cms.gov/files/document/2019-hcpcs-application-summary-may-14-2019-drugs-and-biologicals.pdf **3.** ICD-10-CM tabular list of diseases and injuries. Centers for Disease Control and Prevention. Published April 2022. Accessed May 6, 2025. https://ftp.cdc.gov/pub/health_statistics/nchs/Publications/ICD10CM/2022/icd10cm-tabular-2022-April-1.pdf **4.** XW033MA. Codify website. Accessed May 15, 2025. https://www.aapc.com/codes/pcs-code/XW033MA **5.** XW043MA. Codify website. Accessed May 15, 2025. https://www.aapc.com/codes/pcs-code/XW043MA **6.** CPT® 96365, under therapeutic, prophylactic, and diagnostic injections and infusions (excludes chemotherapy and other highly complex drug or highly complex biologic agent administration). Codify website. Accessed May 2, 2025. https://www.aapc.com/codes/cpt-codes/96365?msockid=151d1a465827668c31c80a7559da67b2 **7.** EAPG listing: effective October 1, 2018. 3M Health Information Systems. Published August 23, 2018. Accessed May 2, 2025. https://dhcf.dc.gov/sites/default/files/dc/sites/dhcf/page_content/attachments/DC%20EAPG%20Relative%20Weights%20Eff%2010-1-18%20DCO18023.pdf

IMPORTANT SAFETY INFORMATION (continued)

Infections (continued)

In patients with primary HLH receiving Gamifant in clinical trials, serious infections such as sepsis, pneumonia, bacteremia, disseminated histoplasmosis, necrotizing fasciitis, viral infections, and perforated appendicitis were observed in 32% of patients.

In patients with HLH/MAS in Still's disease receiving Gamifant in clinical trials, serious infections such as pneumonia, cytomegalovirus infection, cytomegalovirus infection reactivation, and sepsis were observed in 13% of patients.

Evaluate patients for tuberculosis risk factors and test for latent infection prior to initiating Gamifant. Administer tuberculosis prophylaxis to patients at risk for tuberculosis or known to have a positive purified protein derivative (PPD) test result.

Consider prophylaxis for herpes zoster, *Pneumocystis jirovecii*, and fungal infection while receiving Gamifant. Employ surveillance testing during treatment with Gamifant.

Please see additional Important Safety Information throughout and full Prescribing Information for Gamifant.

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Indications and Important Safety Information

INDICATIONS

Gamifant (emapalumab-lzsg) is an interferon gamma (IFNγ)-neutralizing 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.
- HLH/macrophage activation syndrome (MAS) in known or suspected Still's disease, including systemic Juvenile Idiopathic Arthritis (sJIA), with an inadequate response or intolerance to glucocorticoids, or with recurrent MAS.

IMPORTANT SAFETY INFORMATION

Infections

Gamifant may increase the risk of fatal and serious infections with pathogens including mycobacteria, herpes zoster virus, and histoplasma capsulatum. Do not administer Gamifant in patients with these infections until appropriate treatment has been initiated.

In patients with primary HLH receiving Gamifant in clinical trials, serious infections such as sepsis, pneumonia, bacteremia, disseminated histoplasmosis, necrotizing fasciitis, viral infections, and perforated appendicitis were observed in 32% of patients.

In patients with HLH/MAS in Still's disease receiving Gamifant in clinical trials, serious infections such as pneumonia, cytomegalovirus infection, cytomegalovirus infection reactivation, and sepsis were observed in 13% of patients.

Evaluate patients for tuberculosis risk factors and test for latent infection prior to initiating Gamifant. Administer tuberculosis prophylaxis to patients at risk for tuberculosis or known to have a positive purified protein derivative (PPD) test result.

Consider prophylaxis for herpes zoster, *Pneumocystis jirovecii*, and fungal infection while receiving Gamifant. Employ surveillance testing during treatment with Gamifant.

Closely monitor patients receiving Gamifant for signs or symptoms of infection, promptly initiate a complete diagnostic workup appropriate for an immunocompromised patient, and initiate appropriate antimicrobial therapy.

Increased Risk of Infection With Use of Live Vaccines

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 in patients with primary HLH, 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.

Infusion-related reactions in patients with HLH/MAS in Still's disease, including pyrexia, headache, paresthesia, bone pain, pruritic rash, and peripheral coldness, were reported with Gamifant treatment in 13% of patients. Infusion-related reactions were reported as mild in 8% of patients and as moderate in 5% of patients.

Monitor patients for infusion-related reactions, which can be severe. Interrupt the infusion for infusion reactions and institute appropriate medical management before continuing infusion at a slower rate.

Adverse Reactions

Primary HLH

Serious adverse reactions were reported in 53% of patients. The most common serious adverse reactions (≥3%) included infections, gastrointestinal hemorrhage, and multiple organ dysfunction. Fatal adverse reactions occurred in 2 (6%) of patients and included septic shock and gastrointestinal hemorrhage.

The most common adverse reactions were (≥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%).

HLH/MAS

Serious adverse reactions were reported in 12 patients (31%), with the most common serious adverse reaction being pneumonia (5%). Fatal adverse reactions occurred in two patients (5%) and included multiple organ dysfunction and circulatory shock.

The most common adverse reactions (≥10%) for Gamifant included viral infection (44%), rash (21%), anemia (18%), leukopenia (15%), thrombosis (15%), bacterial infections (13%), headache (13%), hyperglycemia (13%), infusion-related reactions (13%), abdominal pain (10%), hypertension (10%), pyrexia (10%), and thrombocytopenia (10%).

Click here for the full Prescribing Information for Gamifant.
For statutory pricing disclosures, please click here for more information.

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