

MEDICATION GUIDE
GAMIFANT® (gam' i fant)
(emapalumab-lzsg)
injection, for intravenous use

What is the most important information I should know about GAMIFANT?

GAMIFANT can cause serious side effects including:

Infections. GAMIFANT is a medicine that affects your immune system and may lower the ability of your immune system to fight infections. GAMIFANT may increase your risk of serious infections that can lead to death. These infections include tuberculosis (TB), histoplasmosis, Herpes zoster infection (shingles) and other infections caused by viruses, fungi or bacteria that can spread throughout the body.

Your healthcare provider will:

- test you for TB before you start treatment with GAMIFANT.
- treat you with a medicine for TB if you are at risk for TB or if you have a known positive TB test.

Infections are common in people treated with GAMIFANT.

Before starting GAMIFANT, tell your healthcare provider if you:

- had TB in the past, or if you or a member of your family have been in recent close contact with someone with TB.
- have ever had a positive TB skin test (PPD).
- currently have or have had history of infections, including histoplasmosis or Herpes zoster (shingles).
- are being treated for an active infection.
- have symptoms of an infection, such as fever, sweat and chills, cough, breathing problems, blood in mucus (phlegm), warm, red, or painful skin or sores on your body.

Your healthcare provider will give you medicine to help prevent certain infections before you receive GAMIFANT. After starting GAMIFANT, tell your healthcare provider if:

- new symptoms of an infection appear.
- symptoms of an infection that you already had when starting GAMIFANT worsen.

Your healthcare provider will monitor you closely for signs and symptoms of infections during treatment with GAMIFANT.

See “**What are the possible side effects of GAMIFANT?**” for more information about side effects.

What is GAMIFANT?

GAMIFANT is a prescription medicine used for the treatment of adults and children (newborn and older) with primary hemophagocytic lymphohistiocytosis (HLH) whose disease has come back or progressed, or other medicines have not worked well enough or cannot be tolerated.

Before you receive GAMIFANT, tell your healthcare provider about all of your medical conditions including if you:

- have an infection (see “**What is the most important information I should know about GAMIFANT?**”)
- have received or are scheduled to receive an immunization (vaccine). You should not receive “live or attenuated-live” vaccines during your treatment with GAMIFANT and for at least 4 weeks after the last dose of GAMIFANT.
- are pregnant or plan to become pregnant. It is not known if GAMIFANT can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if GAMIFANT passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with GAMIFANT.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive GAMIFANT?

- You will receive GAMIFANT through a vein by intravenous (IV) infusion over 1 hour.
- Your healthcare provider will monitor you during the infusion for side effects.
- GAMIFANT is given 2 times a week (every 3 to 4 days).
- Your healthcare provider will do blood tests during your treatment with GAMIFANT to see how well you respond to treatment.
- GAMIFANT is used with another prescription medicine called dexamethasone. You can ask your healthcare provider for information about dexamethasone.

What are the possible side effects of GAMIFANT?

GAMIFANT can cause serious side effects, including:

- See “**What is the most important information I should know about GAMIFANT?**”
- **Infusion reactions.** Infusion reactions are common with GAMIFANT, and can also be severe. Infusion reactions can happen during or shortly after treatment with GAMIFANT. Your healthcare provider may temporarily stop your infusion and treat your symptoms before continuing your infusion if you have severe infusion reactions. Tell your healthcare provider right away if you get any of the following symptoms:

- skin redness
- itching
- fever
- rash
- excessive sweating
- chills
- chest pain
- shortness of breath
- nausea or vomiting
- lightheadedness or dizziness

The most common side effects of GAMIFANT include: high blood pressure (hypertension) and fever.

These are not all of the possible side effects of GAMIFANT.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of GAMIFANT.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your healthcare provider or pharmacist for information about GAMIFANT that is written for health professionals.

What are the ingredients in GAMIFANT?

Active ingredient: emapalumab-lzsg

Inactive ingredients: L-Histidine, L-Histidine monohydrochloride, monohydrate, Polysorbate 80, sodium chloride, and Water for Injection, USP

Manufactured at: Patheon Italia S.p.A. 2° Trav. SX Via Morolense, 5, 03013-Ferentino Italy

Manufactured by: Swedish Orphan Biovitrum AB (publ), Stockholm, Sweden, U.S. License Number 1859

Distributed by: Sobi Inc., 890 Winter Street, Waltham, MA 02451

Product of the United Kingdom

For more information call 1-866-773-5274 or go to www.gamifant.com

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Issued: 05/2019