





There's a lot to consider when you or your child have been diagnosed with primary HLH. We hope you can take comfort in knowing that treatment options are available, and that Gamifant was specifically designed to treat primary HLH. Working with your doctors and learning all you can about Gamifant can help you prepare for the journey ahead.

HLH=hemophagocytic lymphohistiocytosis.

#### 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.

#### **IMPORTANT SAFETY INFORMATION**

**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



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# Before starting GAMIFANT, tell your healthcare provider all of your medical conditions and 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 had a positive TB skin test (purified protein derivative test)
- Currently have an infection or have a 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); or warm, red painful skin or sores on your body
- 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



# **IMPORTANT SAFETY INFORMATION (continued)**

Your healthcare provider will give you medicine to help prevent certain infections before you receive GAMIFANT.

#### Tell your healthcare provider about all the medicines you take,

including prescription and over-the-counter medicines, vitamins, and herbal supplements.

#### 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

#### GAMIFANT can cause serious infusion reactions.

These are common, can also be severe, and 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 Chills
- Itching
  · Chest pain
- Fever
  Shortness of breath
- Rash
  Nausea or vomiting
- Excessive sweating Lightheadedness or dizziness

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

These are not all the possible side effects for GAMIFANT. For more information, ask your healthcare provider. You can also see the full Prescribing Information for GAMIFANT at <u>https://gamifant.com/pdf/</u> Full-Prescribing-Information.pdf.

To report suspected adverse reactions, contact Sobi North America at 1-866-773-5274 or FDA at 1-800-FDA-1088.



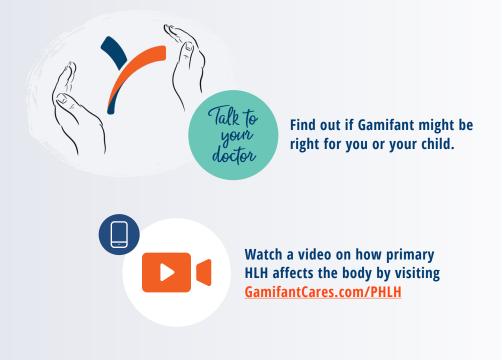
# What is Gamifant?

#### Gamifant is the first and only FDA-approved treatment for primary HLH.

It is made specifically for people with primary HLH who did not have success with other treatments.

#### Your doctor may consider prescribing Gamifant if you or your child:

- Do not improve with other treatments
- Have very bad side effects with other treatments
- Respond to other treatments at first, but then symptoms come back
- Have symptoms that quickly get worse



FDA=Food and Drug Administration.



# How can Gamifant help?

#### Gamifant works by blocking the main cause of primary HLH.

Primary HLH symptoms are caused by inflammation. The inflammation is caused by many different types of cytokines getting out of control. One of them is called interferon gamma (IFNy).

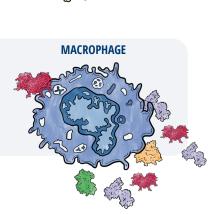
# Cytokines are a type of protein that play an important role in the immune system.

In primary HLH, IFNy connects to another cell called a macrophage. When this happens, macrophages start making more and more cytokines. This leads to inflammation in primary HLH.

Macrophages are a type of white blood cell that helps fight illness.

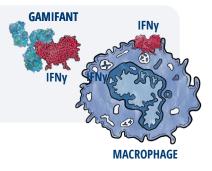
**Gamifant was specifically developed to connect to IFNy** to neutralize its activity. By neutralizing IFNy, Gamifant helps calm inflammation to relieve primary HLH symptoms.

Please see Important Safety Information on pages 2-3. <u>Click here</u> for Patient Medication Guide for Gamifant.



IFNv

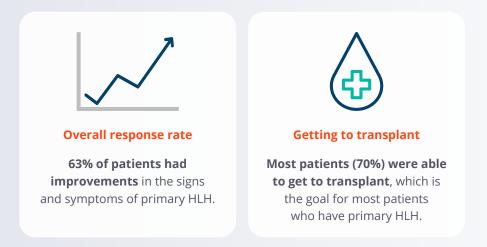
CYTOKINES





# Have other patients with primary HLH used Gamifant?

Gamifant was shown to help treat primary HLH in a clinical trial. It was approved by the FDA in 2018. Since then many patients with primary HLH, like you or your child, have started Gamifant.



# GAMIFANT may increase your risk of infections, including serious infections that can lead to death

Before starting GAMIFANT, tell your healthcare provider all of your medical conditions and 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 had a positive TB skin test (purified protein derivative test)
- Currently have an infection or have a 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); or warm, red painful skin or sores on your body



Learn more about the safety and effectiveness of Gamifant at <u>GamifantCares.com</u>



# How is Gamifant treatment given?

If your doctor prescribes Gamifant, you or your child will most likely get treatment in the hospital. Tell your doctor about all the medicines you or your child take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.



Gamifant is **given by intravenous (IV, or in a vein) infusion**. The infusion will take about an hour. Your doctor or infusion nurse will watch for side effects during the infusion.



Gamifant is **given 2 times a week** (every 3 to 4 days) until you or your child begins preparing for transplant, no longer needs treatment, or experiences unacceptable side effects.



Gamifant is **used with a steroid called dexamethasone**, which is often given on a daily schedule. Over time, your doctor may reduce the amount of dexamethasone.

**Dosing may change throughout treatment based on your or your child's response.** Talk with your healthcare team to learn more.

Medications for TB for at-risk individuals, herpes zoster, *Pneumocystis jirovecii*, and fungal infections are also administered prior to starting Gamifant.



Find out if Gamifant may be an option for you or your child.



## Does Gamifant have any side effects?

Because Gamifant affects the immune system, it may lower your ability to fight infections.

#### Gamifant may increase the risk of serious infections, including:

Tuberculosis (TB)Histoplasmosis

- Other infections caused by viruses, fungi, or bacteria that can spread throughout the body
- Herpes zoster infection (shingles)

Doctors will test you or your child for TB before starting Gamifant, and they may prescribe a treatment for TB if you or your child is at risk or has a positive TB test.

Doctors may also give you or your child treatments to help prevent certain infections before giving you Gamifant.

#### Gamifant can cause serious infusion reactions

Infusion reactions such as rash and fever are common with Gamifant. They usually happen during or right after treatment. Your doctor may stop the infusion and treat symptoms before continuing if you or your child have severe reactions.

#### Other possible side effects

There are some serious side effects that can happen during treatment with Gamifant. Your doctor will look out for high blood pressure (hypertension) and fever.

These are not all of the possible side effects of Gamifant. Talk to your doctor for medical advice about side effects.

Tip

Save your doctor's phone number in your cell phone contacts so that it is always handy.



# What if I have questions about Gamifant?

Your doctor is your partner in treatment and the best source of information. Gamifant Cares Support Services are also available to help.

#### **Gamifant Cares**

Gamifant Cares offers support to help you and your family throughout treatment with Gamifant. A dedicated Gamifant Cares team can help with personalized support and resources including:

- Navigating and understanding the insurance process
- Providing financial assistance information for eligible patients

# Call Gamifant Cares anytime 1.833.597.6540



For more information about Gamifant Cares and other support, visit <u>GamifantCares.com</u>



# Gamifant is a treatment option that may be able to help

Learn more about why your doctor may prescribe Gamifant and what to expect during treatment.



Please see Important Safety Information on pages 2-3. <u>Click here</u> for Patient Medication Guide for Gamifant.



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