

Your *journey* with Gamifant starts here



Gamifant is approved for people with HLH/MAS in known or suspected Still's disease, including systemic Juvenile Idiopathic Arthritis (sJIA), when steroids didn't work well enough, couldn't be tolerated, or with MAS that has come back

If you or someone you care for has sJIA or Still's, it's very important to know about a life-threatening complication that can occur called macrophage activation syndrome (MAS).

Once you're aware of the signs and symptoms of MAS, you can feel more prepared and confident about options for treatment.

HLH=hemophagocytic lymphohistiocytosis.

IMPORTANT SAFETY INFORMATION

Gamifant can cause serious side effects including:

• **Infections.** GAMIFANT 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. **Infections are common in people treated with Gamifant.** Your healthcare provider will:

- Test you for TB before you start Gamifant
- Treat you with a medicine for TB if you are at risk for TB or if you have a known positive TB test

Please see full Important Safety Information on pages 13-14. Click here for full Prescribing Information and Patient Medication Guide for Gamifant.

A little knowledge goes a long way

This brochure is designed to help you learn more about MAS in sJIA or Still's and Gamifant as a possible treatment option. Learning and working with your doctor can help you feel prepared when moving forward with treatment.

CONTENTS

What is MAS in sJIA or Still's?	3-4
Symptoms of MAS	5
Testing for MAS in sJIA or Still's	6
Treating MAS in sJIA or Still's	7
About Gamifant	8-11
Gamifant Cares	12

IMPORTANT SAFETY INFORMATION

Before starting Gamifant, tell your doctor 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 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, or painful skin or sores on your body

Please see full Important Safety Information on pages 13-14. Click here for full Prescribing Information and Patient Medication Guide for Gamifant.

What is MAS in sJIA or Still's?

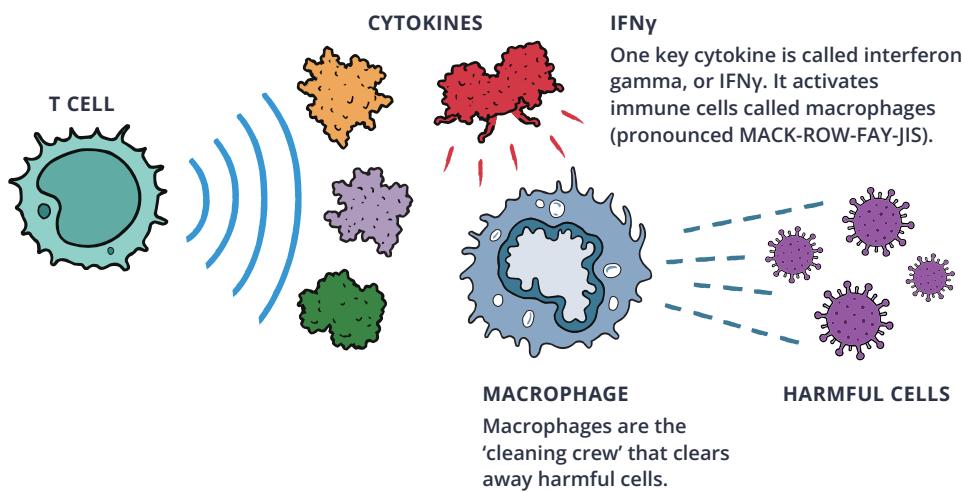
MAS in Still's is a very serious condition. It can happen when the body's immune system tries to fight off harmful cells and causes too much inflammation.

To understand MAS in Still's, let's first see how a healthy immune system works:

When harmful cells are present in the body, immune cells work to destroy them. These immune cells are called T cells.

To do their job, T cells need help from other immune cells.

T cells send out messenger proteins called cytokines (pronounced SIGH-TOE-KINES).



Inflammation is part of the body's healthy, controlled response to harmful cells.

CARE TIP

If possible, it's helpful to find a rheumatologist familiar with MAS in Still's.

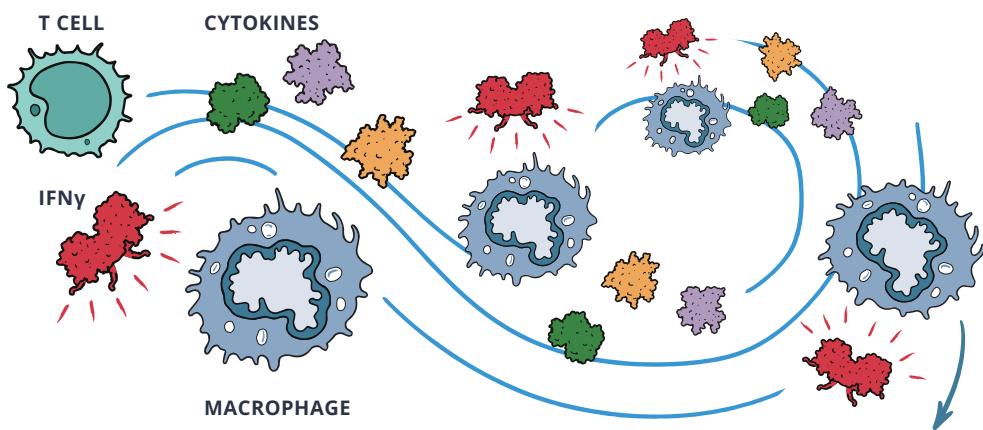
What happens in MAS in Still's?

Now let's look at an immune system experiencing MAS in Still's:

T cells don't work properly. They send out too many cytokines, including IFNy.

Too much IFNy activates an increasing number of macrophages.

So many cytokines and macrophages result in dangerous amounts of inflammation.



Since so many macrophages are activated, the condition is called **macrophage activation syndrome**, or MAS.

High amounts of inflammation are called "hyperinflammation." Hyperinflammation can damage organs such as the heart, liver, spleen, and kidneys.

When MAS in Still's strikes, it may often be confused with a flare of SJIA or Still's. It's important to know the symptoms of MAS to look for.

What are the symptoms of MAS in sJIA or Still's?

Early detection of MAS in Still's is critical

In someone who already has sJIA or Still's, MAS in Still's can come on very quickly. It can show up with 1 or more of these symptoms.



KEY WARNING SIGNS

Long-lasting fever

Rash

Swollen lymph nodes

Yellowing of the eyes and skin (jaundice)

Trouble breathing 

Coughing

Low energy level

Confusion or changes in alertness

Seizures

No appetite

Stomachache, vomiting, or diarrhea

Trouble breathing requires immediate attention; go straight to a hospital emergency room. In the event of any of the other symptoms, call your doctor or go to an emergency room.



CARE TIP

Take pictures of new rashes so you can show them to your doctor or compare to previous ones.

What kinds of tests will the doctor run?

Blood tests can help identify an episode of MAS in Still's

Certain blood test results can be too high or too low in MAS in Still's. These results can help your doctor make a diagnosis and treatment plan.

BLOOD TESTS AND LEVELS TO WATCH FOR

✓ Ferritin (protein that stores iron)	HIGH
✓ Platelet count (cell fragments that help blood clot)	LOW
✓ Triglycerides (type of fat in cells)	HIGH
✓ AST (enzyme of the liver and other organs)	HIGH
✓ Fibrinogen (protein in blood clotting)	LOW



CARE TIP

Talk with your doctor about these test results. They are important in diagnosing and treating MAS in Still's.

AST=aspartate aminotransferase.

How is MAS in sJIA or Still's treated?

When someone has MAS in Still's, doctors may give medicines that reduce inflammation

The standard treatment for MAS in Still's is steroids. Steroids can help reduce inflammation, but they don't always work and not everyone can take them. They also have side effects, especially when taken in high doses for a long time, such as high blood sugar, high blood pressure, and slowed growth.

When steroids aren't enough, or when patients are experiencing side effects, doctors might consider using other medicines. The overall goal would be to find a treatment option that could:



Stop
hyperinflammation



Reduce
the impact of
MAS symptoms



Help
keep the person safe
from organ damage



Lower
the need for steroids

CARE TIP *If you or your loved one is not getting better after treatment with steroids, ask your doctor to consider other available medicines.*

What is Gamifant?

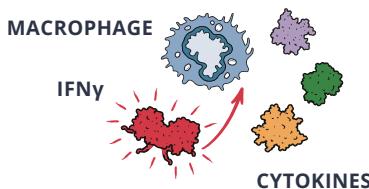
Gamifant is the only FDA-approved treatment for people who have MAS in sJIA or Still's

Gamifant targets IFNy, a key cause of hyperinflammation.

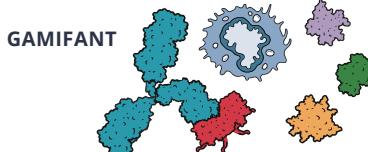
Lowering IFNy helps to control hyperinflammation.

How Gamifant works

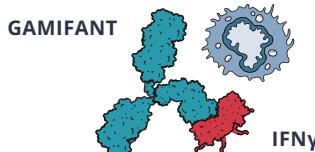
- 1 In MAS, when too much IFNy is activating macrophages, treatment is needed to control the hyperinflammation.



- 2 Gamifant attaches to IFNy to block its activity.



- 3 The amount of cytokines is reduced and hyperinflammation is controlled.



IMPORTANT SAFETY INFORMATION

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

Your healthcare provider may give you medicine to help prevent certain infections before you receive Gamifant and will monitor you closely for signs and symptoms of infections during treatment with Gamifant.

Please see full Important Safety Information on pages 13-14. Click here for full Prescribing Information and Patient Medication Guide for Gamifant.

How effective is Gamifant?

Gamifant was tested in 2 clinical trials for FDA approval

Gamifant was studied in 39 children and adults. These participants had active MAS with Still's including sJIA that could not be controlled by steroids or with MAS that has come back.

The results of the studies supported the approval of Gamifant to be used in patients who have active MAS with Still's including sJIA who experienced 1 or more of the following:



- ✓ Steroid treatment didn't work well enough
- ✓ Steroid treatment could not be tolerated
- ✓ Had another MAS episode during previous treatment

The studies lasted 8 weeks.

IMPORTANT SAFETY INFORMATION

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	• headache	• nausea or vomiting
• itching	• bone pain	• lightheadedness or dizziness
• fever	• chills	• tingling, burning, or numbness
• rash	• chest pain	• cold hands, arms, legs, or feet
• excessive sweating	• shortness of breath	

Please see full Important Safety Information on pages 13-14. Click here for full Prescribing Information and Patient Medication Guide for Gamifant.

How Gamifant performed in the clinical studies

Researchers looked at 8 measures to see if Gamifant worked. If a patient got better in all 8, they were said to have a complete response.*

These are the measures researchers checked and the percentage of patients who got better in each:

MAS ACTIVITY **82%** MAS was resolved or inactive[†]

SIGNS OF INFLAMMATION **84%** Normal ferritin levels
 89% Normal fibrinogen levels
 66% Normal LDH levels

BLOOD CELL COUNTS **87%** Normal platelet count
 92% Normal white blood cell count

LIVER FUNCTION **87%** Normal ALT levels
 94% Normal AST levels

53%
of patients got better
in all 8 measures
(complete response)*

*To measure complete response, researchers used statistics to see if the results were really from the new medicine and not just by chance. However, the analysis wasn't able to prove that these results were due to the treatment.

[†]According to the treating doctor.

ALT=aspartate aminotransferase; LDH=lactate dehydrogenase.

IMPORTANT SAFETY INFORMATION

Before starting Gamifant, tell your doctor about all of your medical conditions including if you:

- have an infection
- have received or are scheduled to receive an immunization (vaccine). You should not receive live or live attenuated vaccines while taking Gamifant and for at least 4 weeks after your last dose of Gamifant
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed

Please see full Important Safety Information on pages 13-14. Click here for full Prescribing Information and Patient Medication Guide for Gamifant.

What are the possible side effects of Gamifant?

The most common adverse reactions reported in $\geq 10\%$ of people in the studies were:

- Viral infection
- Cytomegalovirus (CMV) infection or reactivation (a new herpes viral infection or one that restarts)
- Rash
- Anemia (low levels of red blood cells and hemoglobin, a protein in red blood cells)
- Leukopenia (low white blood cell count)
- Thrombosis (formation of a blood clot inside a blood vessel)
- Bacterial infection
- Headache
- Hyperglycemia (too much sugar in the blood)
- Infusion-related reactions (side effects like fever, chills, or rash after receiving medication through a vein)
- Abdominal pain
- Hypertension (high blood pressure)
- Pyrexia (fever)
- Thrombocytopenia (low platelet levels in the blood)

Twelve patients in the study experienced serious side effects, with pneumonia being most common. Two patients experienced serious health complications including multiple organ dysfunction and circulatory shock and passed away during the study.

What if I have questions about Gamifant?

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

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 at **[833-597-6530]** or
visit [**GamifantCares.com/MAS/supportservices**](http://GamifantCares.com/MAS/supportservices)

Important Safety Information

What is GAMIFANT?

Gamifant (emapalumab-lzsg) is a prescription medicine used for the treatment of hemophagocytic lymphohistiocytosis (HLH) in adults and children (newborn and older) with HLH/macrophage activation syndrome (MAS) in Still's disease, including systemic Juvenile Idiopathic Arthritis (sJIA), when glucocorticoids have not worked well enough or cannot be tolerated, or with MAS that has come back.

IMPORTANT SAFETY INFORMATION

Gamifant can cause serious side effects including:

- **Infections.** GAMIFANT 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. **Infections are common in people treated with Gamifant.** Your healthcare provider will:
 - Test you for TB before you start Gamifant
 - Treat you with a medicine for TB if you are at risk for TB or if you have a known positive TB test

Before starting Gamifant, tell your doctor 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 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, or painful skin or sores on your body

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

Your healthcare provider may give you medicine to help prevent certain infections before you receive Gamifant and will monitor you closely for signs and symptoms of infections during treatment with Gamifant.

Please see additional Important Safety Information on [page 14](#). Click here for [full Prescribing Information](#) and [Patient Medication Guide](#) for Gamifant.

Important Safety Information (cont'd)

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
- headache
- tingling, burning, or numbness
- bone pain
- cold hands, arms, legs, or feet

Before starting Gamifant, tell your doctor about all of your medical conditions including if you:

- have an infection
- have received or are scheduled to receive an immunization (vaccine). You should not receive live or live attenuated vaccines while taking Gamifant and for at least 4 weeks after your last dose of Gamifant
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed

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

The most common side effects of Gamifant in people with HLH/MAS in Still's disease include: viral infection and rash.

These are not all 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.

For people who have MAS in sJIA or Still's when steroids haven't worked well enough or when MAS has come back,

Gamifant is the only FDA-approved treatment option for MAS in sJIA or Still's



In someone who has sJIA or Still's, MAS is a dangerous complication that can come on very quickly.



Gamifant is the only FDA-approved treatment for MAS. It targets IFNy, a key cause of hyperinflammation.



Gamifant is proven to help control hyperinflammation to relieve MAS in Still's symptoms.

Talk to your doctor or visit GamifantCares.com for more information about Gamifant for MAS in Still's.

IMPORTANT SAFETY INFORMATION

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

The most common side effects of Gamifant in people with HLH/MAS in Still's disease include: viral infection and rash.

Please see full Important Safety Information on pages 13-14. Click here for full Prescribing Information and Patient Medication Guide for Gamifant.