

“TODAY, he’s
NOT THINKING
ABOUT PERIODIC
FEVERS.”

Once-monthly ILARIS® (canakinumab)
is the **only** biologic medicine that is
FDA approved to treat FMF,
HIDS/MKD, and TRAPS.



Images shown are not actual
patients or their families.

APPROVED USE

ILARIS® (canakinumab) is a prescription medicine injected by your healthcare provider just below the skin (subcutaneous) used to treat adults and pediatric patients with the following auto-inflammatory Periodic Fever Syndromes:

- Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)
- Hyperimmunoglobulin D Syndrome (HIDS) also known as Mevalonate Kinase Deficiency (MKD)
- Familial Mediterranean Fever (FMF)

IMPORTANT SAFETY INFORMATION

ILARIS can cause serious side effects, including increased risk of serious infections. ILARIS can lower the ability of your immune system to fight infections. Your healthcare provider should:

- test you for tuberculosis (TB) before you receive ILARIS
- monitor you closely for symptoms of TB during treatment with ILARIS
- check you for symptoms of any type of infection before, during, and after treatment with ILARIS

Please see additional Important Safety Information throughout this brochure, and accompanying Consumer Brief Summary.

ILARIS®
(canakinumab)
150 mg subcutaneous injection



IMPORTANT SAFETY INFORMATION (cont)

Tell your healthcare provider right away if you have any symptoms of an infection such as fever, sweats or chills, cough, flu-like symptoms, weight loss, shortness of breath, blood in your phlegm, sores on your body, warm or painful areas on your body, diarrhea or stomach pain, or feeling very tired.

You should not receive ILARIS if you are allergic to canakinumab or any of the ingredients in ILARIS.



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ILARIS May Be Right for Your Child

Everyday life is filled with a lot of uncertainties when your child has a **Periodic Fever Syndrome**. As a parent, you just don't know if and when flares will happen, and all you want is for your child to live in the moment.

Once-monthly ILARIS® (canakinumab) is an injectable biologic medicine that's **proven to help provide relief** from 3 types of Periodic Fevers: Familial Mediterranean Fever (FMF), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), and Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS).

Taking care of a child with Periodic Fevers can leave you feeling alone, but **we're here to help**. In this brochure, you'll learn how ILARIS works to help treat your child's FMF, HIDS/MKD, or TRAPS. You'll also learn about the full range of services offered through ILARIS Companion. Then, ask your child's doctor if ILARIS may be right for your child.

Sincerely,
The ILARIS Team



STUDY Results

ILARIS[®]
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STUDY RESULTS

SAFETY
CONSIDERATIONS

HOW IT WORKS

DOSING & SUPPORT

HELPFUL TIPS

Proven Results with ILARIS

ILARIS® (canakinumab) is the only once-monthly injectable biologic medicine that's FDA approved to treat the following 3 types of Periodic Fevers:

- FMF** Familial Mediterranean Fever (FMF)
- HIDS/MKD** Hyperimmunoglobulin D Syndrome (HIDS)/ Mevalonate Kinase Deficiency (MKD)
- TRAPS** Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)

The FDA approval was based on a study that included **181 children and adults**.

IMPORTANT SAFETY INFORMATION (cont)

Before receiving ILARIS, tell your healthcare provider about all your medical conditions, including if you:

- think you have or are being treated for an active infection
- have symptoms of infection
- have a history of infections that keep coming back
- have a history of low white blood cells
- have or have had HIV, Hepatitis B, or Hepatitis C
- are scheduled to receive any immunizations (vaccines). You should not get 'live vaccines' if you are receiving ILARIS

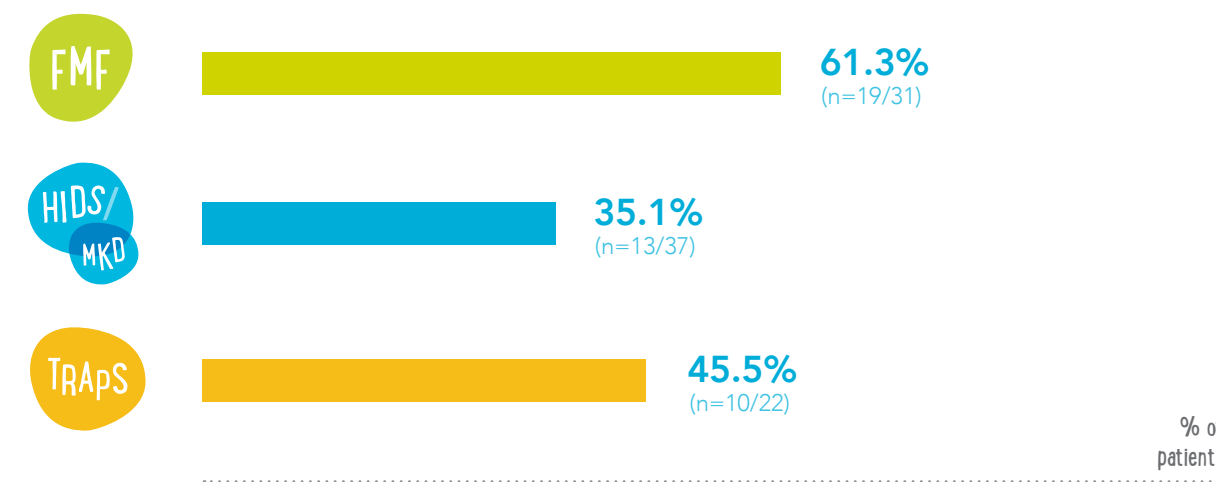


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ILARIS Helps Provide Fast and Sustained Relief*

In a clinical study, people with FMF, HIDS/MKD, or TRAPS were given ILARIS and evaluated for a complete response. A complete response meant that at **day 15 and throughout the entire 16-week treatment period**, they had minimal or no disease activity based on their PGA[†] and CRP[‡] measurements.

Minimal to No Disease Activity at Day 15 Through Week 16



*Study participants were assessed and given a single PGA score based on several signs and symptoms, including:

FMF: chest pain, abdominal pain, arthralgia/arthritis (painful and/or swollen joints), skin rash

HIDS/MKD: lymphadenopathy (swollen lymph nodes), canker sores (aphthous ulcers), abdominal pain

TRAPS: skin rash, musculoskeletal pain, abdominal pain, eye manifestations

[†]Physician's Global Assessment (PGA) is a 5-point scale used to evaluate the overall disease severity of a patient.

[‡]C-reactive protein (CRP) is a blood test to measure inflammation in the body.

“**TODAY,** PERIODIC
FEVERS
should
not be allowed at the
BIG KIDS’ table.”

SAFETY CONSIDERATIONS

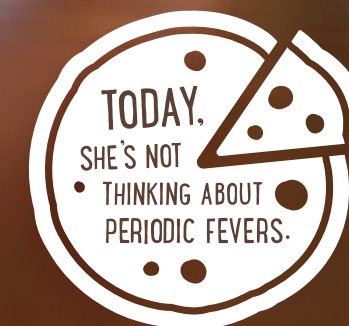
IMPORTANT SAFETY INFORMATION (cont)

Before receiving ILARIS, tell your healthcare provider about all your medical conditions, including if you: (cont)

- are pregnant or planning to become pregnant. It is not known if ILARIS will harm your unborn baby. Tell your healthcare provider right away if you become pregnant while receiving ILARIS
- received canakinumab while you were pregnant. It is important that you tell your baby’s healthcare provider before any vaccinations are given to your baby within 4-12 months after you received your last dose of canakinumab before giving birth
- are breastfeeding or planning to breastfeed. It is not known if ILARIS passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you receive ILARIS

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(canakinumab)
150 mg subcutaneous injection

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SAFETY
CONSIDERATIONS

HOW IT WORKS

DOSING & SUPPORT

HELPFUL TIPS



ILARIS Safety Considerations



Important Safety Information (cont)

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

- medicines that affect the immune system
- medicines called interleukin-1 (IL-1) blocking agents such as Kineret® (anakinra) or Arcalyst® (rilonacept)
- medicines called Tumor Necrosis Factor (TNF) inhibitors such as Enbrel® (etanercept), Humira® (adalimumab), Remicade® (infliximab), Simponi® (golimumab), or Cimzia® (certolizumab pegol)
- medicines that affect enzyme metabolism

Ask your healthcare provider for a list of these medicines if you are not sure.

Important Safety Information (cont)

ILARIS can cause serious side effects including:

- **serious infections**
- **decreased ability of the body to fight infections (immunosuppression).** For people treated with medicines that cause immunosuppression like ILARIS, the chances of getting cancer may increase
- **allergic reactions.** Allergic reactions can happen while receiving ILARIS. Call your healthcare provider right away if you have any of these symptoms of an allergic reaction: difficulty breathing or swallowing, nausea, dizziness or feeling faint, rash, itching or hives, palpitations (feels like your heart is racing), or low blood pressure
- **risk of infection with live vaccines.** You should not get live vaccines if you are receiving ILARIS. Tell your healthcare provider if you are scheduled to receive any vaccines

ILARIS was specifically studied and FDA approved for children and adults with FMF, HIDS/MKD, or TRAPS.



During the study:

No kids or adults stopped treatment with ILARIS due to injection-site reactions. **10.1% of people** experienced injection-site reactions; all were mild or moderate.

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ILARIS[®]
(canakinumab)
150 mg subcutaneous injection

HOW ILARIS WORKS

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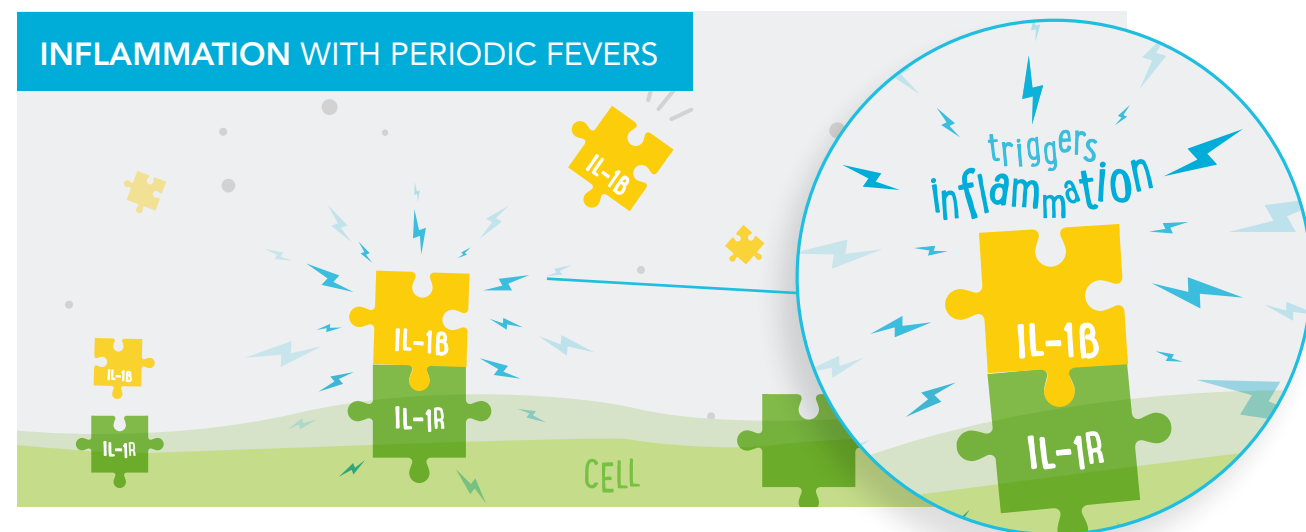
HOW IT WORKS

DOSING & SUPPORT

HELPFUL TIPS

How ILARIS Works

To understand how ILARIS® (canakinumab) works, it's important to start with the role of the immune system in Periodic Fevers and how inflammation (the body's way of protecting itself against sickness or injury) gets triggered in the body.

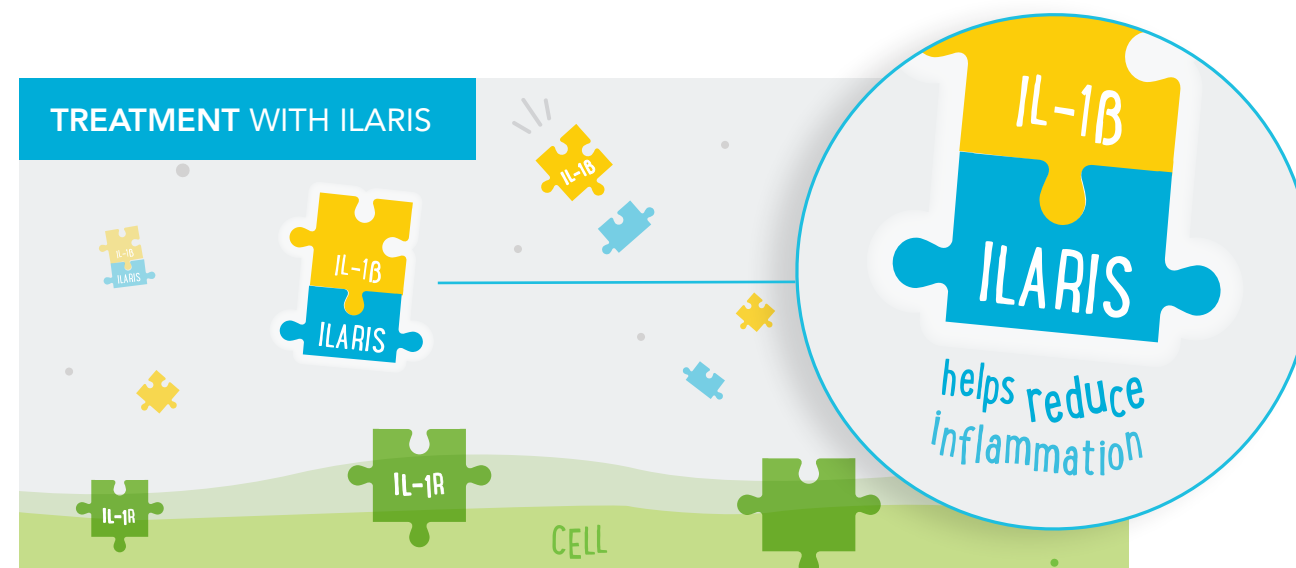


IL-1 β Is a Key Cause of Inflammation in Periodic Fevers

- For a child with Periodic Fevers, the immune system (the body's natural defense system that protects against "foreign" invaders) produces too much of a substance called a cytokine
- Too much of a cytokine called interleukin 1 beta (IL-1 β) is an important cause of inflammation in Periodic Fevers. When IL-1 β attaches to interleukin-1 receptors (IL-1R), the immune system triggers inflammation

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ILARIS Targets IL-1 β to Help Reduce Inflammation

- ILARIS is a different kind of treatment for Periodic Fevers. It's a biologic medicine, designed to target a specific source of inflammation. ILARIS targets IL-1 β
- By attaching to IL-1 β , ILARIS helps to block its interaction with IL-1R
- This action helps to stop the immune system from triggering inflammation

IMPORTANT SAFETY INFORMATION (cont)

The most common side effects of ILARIS when used for the treatment of TRAPS, HIDS/MKD, and FMF: cold symptoms, upper respiratory tract infection, runny nose, sore throat, nausea, vomiting, and diarrhea (gastroenteritis), and injection site reactions (such as redness, swelling, warmth, or itching).

Tell your healthcare provider about any side effect that bothers you or does not go away.

“**TODAY,** PeRiodic
FeVeRS
aREn't coMING alonG
for
this **RiDe.**”

DOSING & SUPPORT

IMPORTANT SAFETY INFORMATION (cont)

What is Macrophage Activation Syndrome (MAS)?

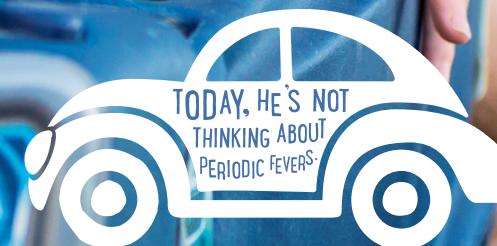
MAS is a syndrome associated with Still's disease and some other auto-inflammatory diseases like HIDS/MKD that can lead to death. Tell your healthcare provider right away if your AOSD or SJIA symptoms get worse or if you have any of these symptoms of an infection:

- a fever lasting longer than 3 days
- a cough that does not go away
- redness in one part of your body
- warm feeling or swelling of your skin

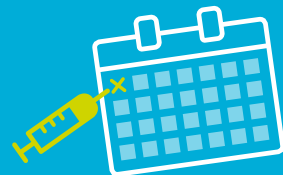
You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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Once-Monthly Dosing of ILARIS



ILARIS® (canakinumab) is a once-a-month injection. Every 4 weeks, a doctor or nurse will give your child a subcutaneous injection of ILARIS, which means it's administered right underneath the skin.

ILARIS Companion

Caring for a child with Periodic Fevers isn't easy, but our team of professionals is here to help support you. ILARIS Companion is here to help you and your family navigate the treatment journey, providing resources to help you access and afford treatment.

For questions about
ILARIS Companion, call **866-972-8315**

ILARIS Home Health Nurse Service

At your doctor's request, a certified home health nurse can administer your child's ILARIS injections in the comfort of your own home. The ILARIS home health nurse:

- Gives your child his or her ILARIS injection—**giving you that moment to focus on comforting your child**
- Can help make sure that your child receives his or her dose of ILARIS on schedule each month
- Comes at **no cost** to patients



This service is available



Ask your
child's doctor to call us.

*and Puerto Rico.

Access to ILARIS

We're committed to helping you get access to ILARIS. Our representatives work with you and your child's doctor to **help you get started**, including:

- Contacting your insurance company
- Providing co-pay* assistance for eligible patients with commercial insurance
- Verifying insurance benefits and investigation of coverage
- Providing information about alternative assistance options for uninsured patients
- Addressing coverage issues
- Assisting with prior authorization and appeals, if needed

*Limitations apply. Please contact ILARIS Companion at 866-972-8315 for more information.

IMPORTANT SAFETY INFORMATION (cont)

ILARIS can cause serious side effects, including increased risk of serious infections.

ILARIS can lower the ability of your immune system to fight infections. Your healthcare provider should:

- test you for tuberculosis (TB) before you receive ILARIS
- monitor you closely for symptoms of TB during treatment with ILARIS
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Words of Encouragement

Most people don't understand what life is like when someone in your family has a rare and complex disease like Periodic Fevers. We spoke with parents like you, and here are some thoughts they found helpful to encourage you to continue to be your child's best advocate:



Educate

friends and family about your child's condition.



Lead

the way for your child.



Listen

to what your gut tells you.



Allow

yourself to enjoy the little moments.



State

your treatment goals and expectations.



Never STOP searching

for the latest information about Periodic Fevers.



PUSH

for more information. Get the answers you need.



SUPPORT

your child and encourage him or her to speak up.



IMPORTANT SAFETY INFORMATION (cont)

Tell your healthcare provider right away if you have any symptoms of an infection such as fever, sweats or chills, cough, flu-like symptoms, weight loss, shortness of breath, blood in your phlegm, sores on your body, warm or painful areas on your body, diarrhea or stomach pain, or feeling very tired.

You should not receive ILARIS if you are allergic to canakinumab or any of the ingredients in ILARIS.

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For more information, talk to your
child's doctor and visit ILARIS.com.



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East Hanover, New Jersey 07936-1080

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ILARIS[®]
(canakinumab)
150 mg subcutaneous injection

ILA-1390450

ILARIS® (i-LAHR-us) (canakinumab) injection for subcutaneous use

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

ILARIS can cause serious side effects, including:

- **Increased risk of serious infections.** ILARIS can lower the ability of your immune system to fight infections. Your healthcare provider should:
 - test you for tuberculosis (TB) before you receive ILARIS
 - monitor you closely for symptoms of TB during treatment with ILARIS
 - check you for symptoms of any type of infection before, during, and after your treatment with ILARIS

Tell your healthcare provider right away if you have any symptoms of an infection such as fever, sweats or chills, cough, flu-like symptoms, weight loss, shortness of breath, blood in your phlegm, sores on your body, warm or painful areas on your body, diarrhea or stomach pain, or feeling very tired.

What is ILARIS?

ILARIS is a prescription medicine injected by your healthcare provider just below the skin (subcutaneous) used to treat adults and children with the following Periodic Fever Syndromes (PFS):

- Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)
- Hyperimmunoglobulin D Syndrome (HIDS) also known as Mevalonate Kinase Deficiency (MKD)
- Familial Mediterranean Fever (FMF)

Who should not receive ILARIS?

- Do not receive ILARIS if you are allergic to canakinumab or any of the ingredients in ILARIS. See the Medication Guide for a complete list of ingredients in ILARIS.

What should I tell my healthcare provider before receiving ILARIS?

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

- think you have or are being treated for an active infection
- have symptoms of an infection
- have a history of infections that keep coming back
- have a history of low white blood cells
- have or have had HIV, Hepatitis B, or Hepatitis C
- are scheduled to receive any immunizations (vaccines). You should not get 'live vaccines' if you are receiving ILARIS.
- are pregnant or planning to become pregnant. It is not known if ILARIS will harm your unborn baby. Tell your healthcare provider right away if you become pregnant while receiving ILARIS.
- received ILARIS while you were pregnant. It is important that you tell your baby's healthcare provider before any vaccinations are given to your baby within 4-12 months after you received your last dose of ILARIS before giving birth.
- are breastfeeding or planning to breastfeed. It is not known if ILARIS passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you receive ILARIS.

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

- medicines that affect your immune system
- medicines called IL-1 blocking agents such as Kineret® (anakinra), Arcalyst® (rilonacept)
- medicines called Tumor Necrosis Factor (TNF) inhibitors such as Enbrel® (etanercept), Humira® (adalimumab), Remicade® (infliximab), Simponi® (golimumab), or Cimzia® (certolizumab pegol)
- medicines that affect enzyme metabolism

Ask your healthcare provider for a list of these medicines if you are not sure.

Brief Summary of Important Risk Information

The risk information provided here is not comprehensive. To learn more, talk about ILARIS with your healthcare provider or pharmacist. For the FDA-approved product labeling, call 1-877-452-7471 or visit www.ILARIS.com.

How will I receive ILARIS?

- ILARIS is given by your healthcare provider every 4 weeks for TRAPS, HIDS/MKD, and FMF.

What are the possible side effects of ILARIS?

ILARIS can cause serious side effects, including:

- See "What is the most important information I should know about ILARIS?"
- **decreased ability of your body to fight infections (immunosuppression).** For people treated with medicines that cause immunosuppression like ILARIS, the chances of getting cancer may increase.
- **allergic reactions.** Allergic reactions can happen while you are receiving ILARIS. Call your healthcare provider right away if you have any of these symptoms of an allergic reaction:
 - difficulty breathing or swallowing, nausea, dizziness or feeling faint, rash, itching or hives, palpitations (feels like your heart is racing), low blood pressure.
- **risk of infection with live vaccines.** You should not get live vaccines if you are receiving ILARIS. Tell your healthcare provider if you are scheduled to receive any vaccines.

The most common side effects of ILARIS for TRAPS, HIDS/MKD, and FMF include:

- cold symptoms, upper respiratory tract infection, runny nose, sore throat, nausea, vomiting and diarrhea (gastroenteritis), and injection site reactions (such as redness, swelling, warmth, itching).

Tell your healthcare provider about any side effect that bothers you or does not go away. These are not all the possible side effects of ILARIS. For more information, ask your healthcare provider or pharmacist.

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 ILARIS.

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

What are Periodic Fever Syndromes such as TRAPS, HIDS/MKD, and FMF?

Periodic Fever Syndromes is the name for several different auto-inflammatory diseases, including CAPS, TRAPS, HIDS/MKD, and FMF. People with these diseases cannot keep certain chemicals made by their body (interleukin-1 beta, also called IL-1 β) at the correct level. All these diseases have symptoms that often come and go, with irritated body parts (inflammation) and elevated body temperature (fever). These conditions have a dysregulation of IL-1 β production and share similar clinical features of recurrent episodes of inflammation and fever.

What is Macrophage Activation Syndrome (MAS)?

MAS is a syndrome associated with Still's disease and some other autoinflammatory diseases like HIDS/MKD that can lead to death. Tell your healthcare provider right away if your AOSD or SJA symptoms get worse or if you have any of these symptoms of an infection: a fever lasting longer than 3 days, a cough that does not go away, redness in one part of your body, warm feeling or swelling of your skin.

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