

FOR PEOPLE LIVING
WITH **PERIODIC FEVER
SYNDROMES (PFS)**

IN THE
DAYS
AHEAD



I WANT TO
FOCUS ON
COOKING,
NOT MY PFS.

Images are not actual patients.

ILARIS[®]
(canakinumab)
150 mg subcutaneous injection

APPROVED USE

ILARIS[®] (canakinumab) is a prescription medicine injected by your healthcare provider just below the skin (subcutaneous) used to treat adult and children with the following autoinflammatory 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

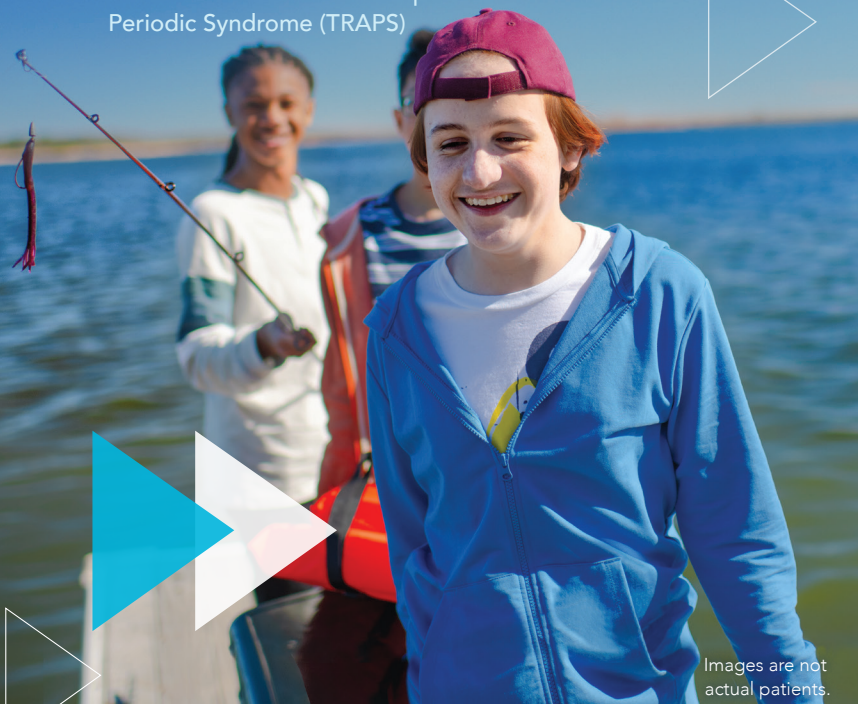
Please see additional Important Safety Information throughout the brochure. Click here for the full [Prescribing Information](#), including [Medication Guide](#), for ILARIS.

What are Periodic Fever Syndromes?

Periodic Fever Syndromes (PFS) are a group of very rare and chronic autoinflammatory diseases that can affect both children and adults. Most Periodic Fever Syndromes are caused by gene mutations that affect the immune system. These mutations trigger an inflammatory response that can cause symptoms including: **fever, rash, painful muscles and/or joints, and others.**

THESE ARE 3 TYPES OF PERIODIC FEVER SYNDROMES THAT ILARIS® TREATS:

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



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AUTOINFLAMMATORY



AUTOIMMUNE

Although their symptoms can be similar, and both trigger a reaction from the immune system, autoinflammatory diseases are not the same as autoimmune diseases.

Your immune system is the body's natural defense against "foreign" invaders. But you have two immune systems in your body: innate and adaptive. Your innate immune system is the one you were born with, while your adaptive immune system is the one you develop over time, based on your life.

With an **autoinflammatory disease**, symptoms occur due to problems in the innate immune system, whereas **autoimmune disease** symptoms come from the adaptive immune system.

With PFS, the immune system triggers inflammation even when there's no infection to fight.

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.

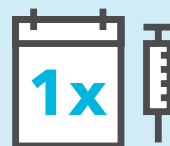
Do not receive ILARIS if you are allergic to canakinumab or any of the ingredients in ILARIS.

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
- have recently received or are scheduled to receive any vaccinations
 - You should be brought up to date with all age required vaccines before starting treatment with ILARIS
 - You should not receive "live" vaccines while you are being treated with ILARIS and until your healthcare provider tells you that your immune system is no longer weakened

ILARIS may be an option for you or your child

ILARIS® is a treatment that's FDA approved to treat FMF, HIDS/MKD, and TRAPS by once-monthly administration.



ONCE-MONTHLY
TREATMENT WITH
PROVEN RESULTS



FDA APPROVED IN THE
UNITED STATES TO TREAT
FMF, HIDS/MKD, AND TRAPS



TARGETS AN IMPORTANT
CAUSE OF SYMPTOMS
OF THESE PFS

It's important to know that these PFS (FMF, HIDS/MKD, or TRAPS) are not contagious. In fact, many PFS are genetic diseases, meaning they can be passed down from family members, although the disease can occur on its own. These inherited diseases can trigger inflammation and other PFS symptoms.

IMPORTANT SAFETY INFORMATION (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 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 to 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 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)

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FMF: symptoms & results with ILARIS

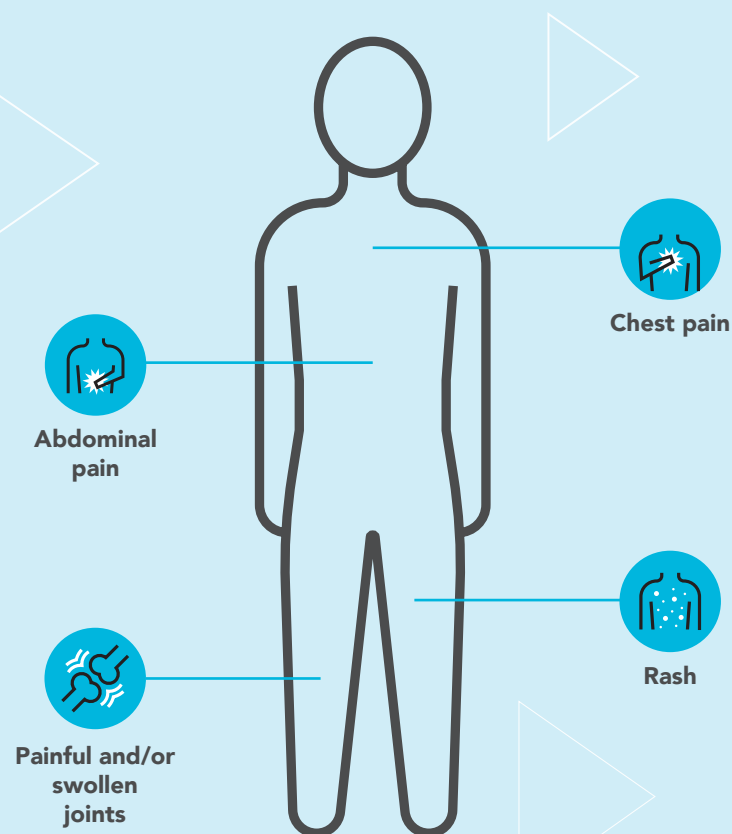
ILARIS® is the only injectable biologic medicine that's FDA approved to treat Familial Mediterranean Fever (FMF) by once-monthly administration. The FDA approval was based on a study that included **181 children and adults with FMF, HIDS/MKD, or TRAPS**.



Images are not actual patients.

FMF

KEY SIGNS AND SYMPTOMS OF FMF ASSESSED IN THE PGA SCORE



ILARIS HELPS PROVIDE FAST & SUSTAINED RELIEF*

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

PATIENTS WITH MINIMAL TO NO DISEASE ACTIVITY AT DAY 15 AND THROUGHOUT THE ENTIRE 16-WEEK TREATMENT PERIOD:

61.3%
(19/31)

*Study participants were assessed and given a single PGA score based on several signs and symptoms. CRP measurements were also taken.

†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.

IMPORTANT SAFETY INFORMATION (cont)

- medicines that affect enzyme metabolism

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

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

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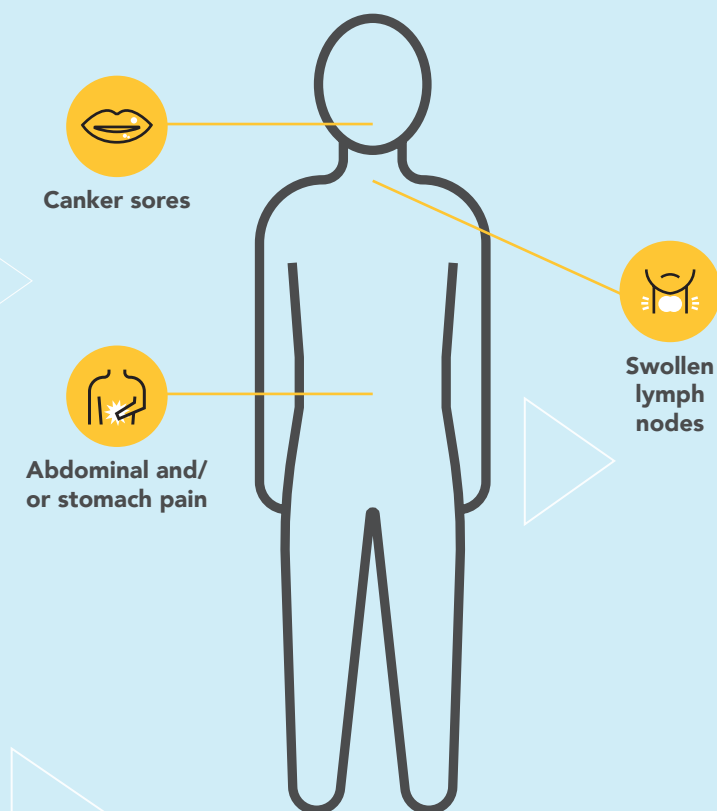
HIDS/MKD: symptoms & results with ILARIS

ILARIS® is the only injectable biologic medicine that's FDA approved to treat Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) by once-monthly administration. The FDA approval was based on a study that included **181 children and adults with FMF, HIDS/MKD, or TRAPS**.



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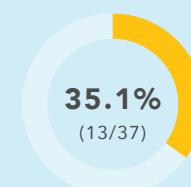
KEY SIGNS AND SYMPTOMS OF HIDS/MKD ASSESSED IN THE PGA SCORE



ILARIS HELPS PROVIDE FAST & SUSTAINED RELIEF*

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

PATIENTS WITH MINIMAL TO NO DISEASE ACTIVITY AT DAY 15 AND THROUGHOUT THE ENTIRE 16-WEEK TREATMENT PERIOD:



*Study participants were assessed and given a single PGA score based on several signs and symptoms. CRP measurements were also taken.

[†]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.

IMPORTANT SAFETY INFORMATION (cont)

- 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 when used for the treatment of 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, or itching).

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

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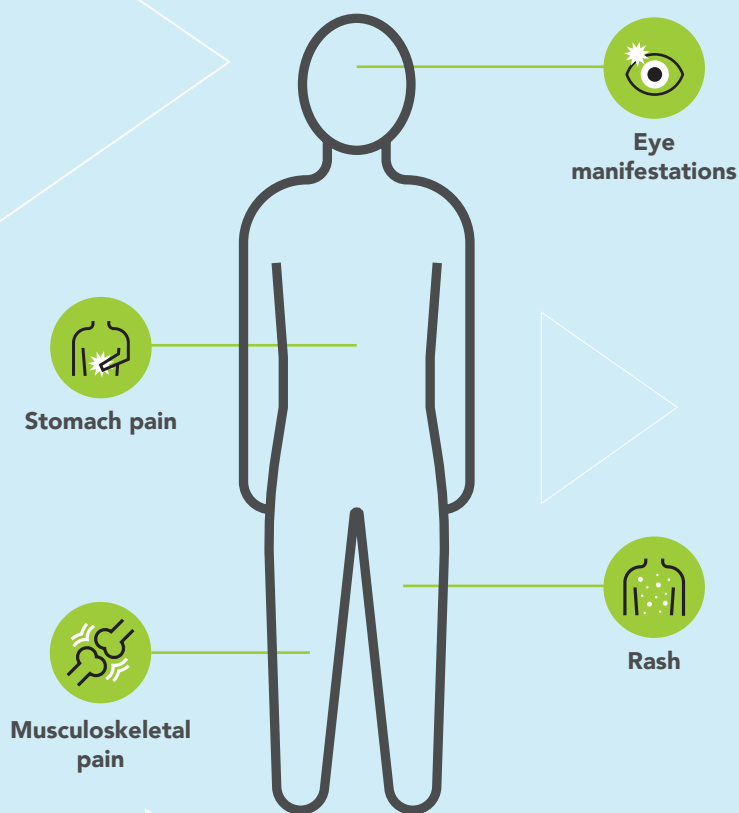
Please see additional Important Safety Information throughout the brochure. Click here for the full [Prescribing Information](#), including [Medication Guide](#), for ILARIS.

TRAPS: symptoms & results with ILARIS

ILARIS® is the only injectable biologic medicine that's FDA approved to treat Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) by once-monthly administration. The FDA approval was based on a study that included **181 children and adults with FMF, HIDS/MKD, or TRAPS.**

Images are not actual patients.

KEY SIGNS AND SYMPTOMS OF TRAPS ASSESSED IN THE PGA SCORE



ILARIS HELPS PROVIDE FAST & SUSTAINED RELIEF*

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

PATIENTS WITH MINIMAL TO NO DISEASE ACTIVITY AT DAY 15 AND THROUGHOUT THE ENTIRE 16-WEEK TREATMENT PERIOD:

45.5%
(10/22)

*Study participants were assessed and given a single PGA score based on several signs and symptoms. CRP measurements were also taken.

†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.

IMPORTANT SAFETY INFORMATION (cont)

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 your Adult-Onset Still's Disease (AOOS) or Systemic Juvenile Idiopathic Arthritis (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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ILARIS safety considerations



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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

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
- check you for symptoms of any type of infection before, during, and after 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.

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

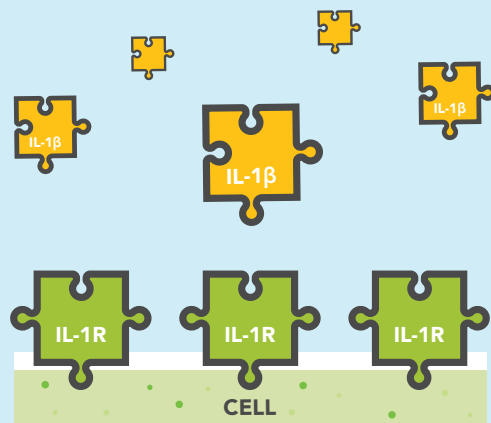
Before receiving ILARIS, tell your healthcare provider about all your medical conditions, including if you:

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- 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
- have recently received or are scheduled to receive any vaccinations
 - You should be brought up to date with all age required vaccines before starting treatment with ILARIS
 - You should not receive “live” vaccines while you are being treated with ILARIS and until your healthcare provider tells you that your immune system is no longer weakened
- 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

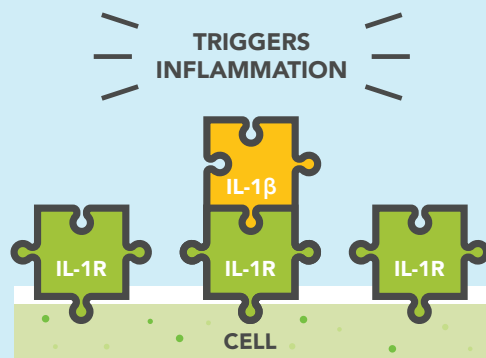
How ILARIS works

IL-1 β IS A KEY CAUSE OF INFLAMMATION IN PFS

In patients with PFS (FMF, HIDS/MKD, or TRAPS), the immune system produces too much of or is too sensitive to a substance called a cytokine, including interleukin-1 beta (IL-1 β), which can lead to inflammation.



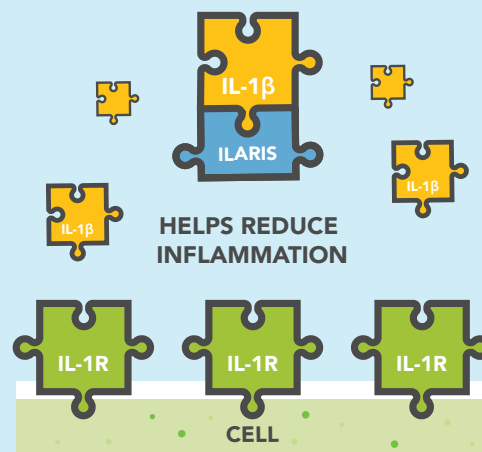
When IL-1 β attaches to interleukin-1 receptors (IL-1R), the immune system triggers inflammation.



ILARIS TARGETS IL-1 β TO HELP REDUCE INFLAMMATION

ILARIS® is 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)

- 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 to 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

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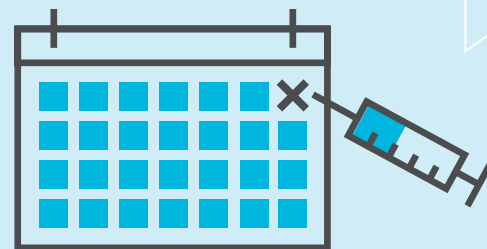
How to take ILARIS



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ILARIS[®] HAS ONCE-MONTHLY DOSING

Every 4 weeks, a doctor or nurse will give you or your child a subcutaneous injection (administered right under the skin).

At a doctor's request, a **home health nurse** can be sent to your home to administer your or your child's monthly ILARIS injection. See the following page for more information.

IMPORTANT SAFETY INFORMATION (cont)

- 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.

ILARIS can cause serious side effects, including:

- serious infections
- 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 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

Get continuous support with ILARIS Companion

ILARIS Companion is here to help you navigate the treatment process, from working with your health insurance and specialty pharmacy to accessing and administering treatment.



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Co-pay savings offer*: Designed to make ILARIS[®] more affordable for eligible, commercially insured patients. Eligible patients **may pay as little as \$30** every time an ILARIS prescription is filled. Additional limitations apply.



Support: Verify health plan benefits, provide information about financial assistance options, and help provide resources and information for prior authorization and appeals, if needed.



Home Health Nurse Service: At the request of a doctor, and if you are eligible,[†] a home health nurse can administer your or your child's ILARIS injection in your own home. This service is available in all 50 states and Puerto Rico. Ask your doctor if this could be an option for you or your child.

- Nurse visits help meet your treatment schedule
- Nurse administers the ILARIS injection
- There are no additional costs for eligible patients

TO CONNECT WITH ILARIS COMPANION, CALL 1-866-972-8315.

*Limitations apply. Call ILARIS Companion at 1-866-972-8315 for more information. **This offer is not valid under Medicare, Medicaid, or any other federal or state program.** Novartis reserves the right to rescind, revoke, or amend this program without notice.

[†]This program is only available for patients with an approved indication for ILARIS.

Words of encouragement

We spoke with patients and parents like you, and here are some thoughts they had to help you on your treatment journey:



EDUCATE FRIENDS AND FAMILY



LISTEN TO YOUR GUT



STATE TREATMENT GOALS AND EXPECTATIONS



PUSH FOR MORE INFORMATION AND GET THE ANSWERS YOU NEED



ENJOY THE LITTLE MOMENTS



NEVER STOP SEARCHING FOR THE LATEST INFORMATION ABOUT PFS

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LEARN MORE ABOUT PFS

Visit any of the websites below to get more information:

The Autoinflammatory Alliance
www.autoinflammatory.org

Genetics Home Reference
ghr.nlm.nih.gov

The Portal for Rare Diseases and Orphan Drugs
www.orpha.net

National Organization for Rare Disorders (NORD)
www.rarediseases.org

Arthritis Foundation
www.arthritis.org

The links to external websites above are being provided as a convenience and for informational purposes only; they do not constitute an endorsement or an approval by Novartis Pharmaceuticals Corporation ("Novartis") of the linked websites, or the information, products, or services contained on these websites. Novartis does not exercise any editorial control over the information you may find at these locations.

FOR OUR DOWNLOADABLE
SYMPTOM TRACKER AND
MORE RESOURCES, VISIT
BIT.LY/PFSresources
OR SCAN THE QR CODE
WITH YOUR PHONE.



IMPORTANT SAFETY INFORMATION (cont)

- 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 when used for the treatment of 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, or itching).

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

**IN THE DAYS AHEAD, YOU WANT TO
FIND ANSWERS, NOT MORE QUESTIONS.**

Use this open space to record questions you may have during this time.

[illegible][illegible]

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TO LEARN MORE ABOUT
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