

FOR PEOPLE LIVING WITH
**CRYOPYRIN-ASSOCIATED
PERIODIC SYNDROMES (CAPS)**

**IN THE
DAYS
AHEAD**

**I WANT TO FOCUS
ON PANCAKES,
NOT CAPS.**



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 adults and children aged 4 years and older who have autoinflammatory diseases called Cryopyrin-Associated Periodic Syndromes (CAPS), including:

- Familial Cold Autoinflammatory Syndrome (FCAS)
- Muckle-Wells Syndrome (MWS)

It is not known if ILARIS is safe and effective when used to treat CAPS in children under 4 years of age.

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 CAPS?

Cryopyrin-associated periodic syndromes (CAPS) are a group of rare, genetic autoinflammatory diseases that include:

- ▶ **FAMILIAL COLD AUTOINFLAMMATORY SYNDROME (FCAS)**
- ▶ **MUCKLE-WELLS SYNDROME (MWS)**

Children can develop CAPS at any point throughout childhood, but FCAS symptoms typically appear during infancy or early childhood, while MWS can appear during early adolescence.

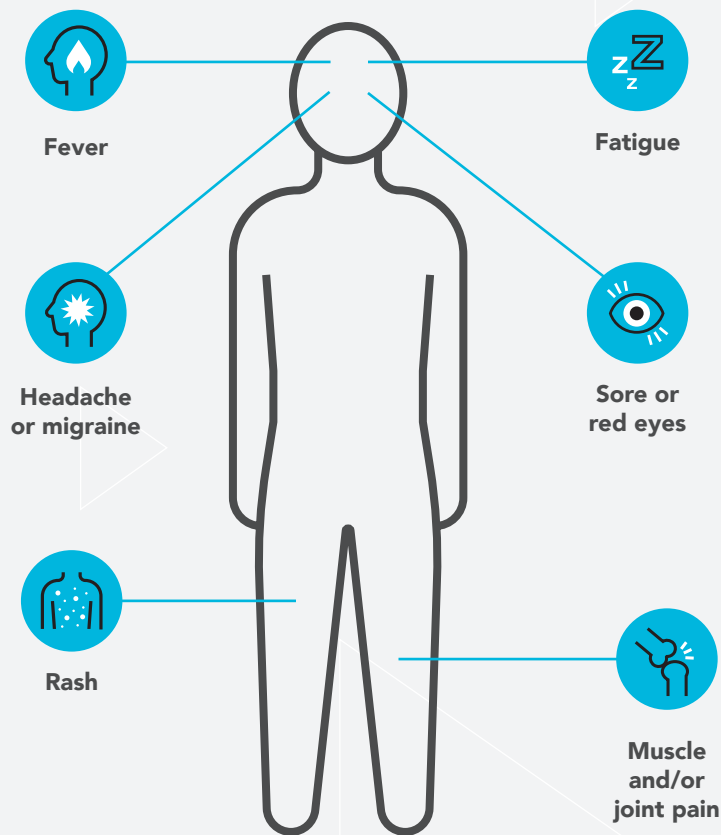


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COMMON SYMPTOMS OF CAPS



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

Who gets CAPS?

CAPS are a group of rare autoinflammatory diseases that are estimated to affect about **1 in 1 million** people in the United States.



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**A CHILD BORN TO A PARENT WITH CAPS HAS
A 50% CHANCE OF GETTING THE DISEASE**



It's important to know that CAPS are not contagious. In fact, CAPS are a group of dominant genetic diseases that are generally passed on from other family members.

Usually, CAPS can be traced back for generations. For some people, though, there is no previous family history of CAPS.

IMPORTANT SAFETY INFORMATION (cont)

- 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
- 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

CAPS are a group of rare autoinflammatory diseases



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

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 your 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.

Diagnosing CAPS



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CAPS can be difficult to diagnose because the symptoms are similar to those of other common conditions. Some people experience symptoms for many years before receiving a diagnosis, while others may live with CAPS without ever being diagnosed.

CAPS SYMPTOMS MAY BE TRIGGERED BY:



EXPOSURE TO COLD



PHYSICAL EXERCISE



A DROP IN TEMPERATURE



STRESS

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

The most common side effects of ILARIS when used for the treatment of CAPS include: cold symptoms, diarrhea, flu (influenza), runny nose, headache, cough, body aches, nausea, vomiting, and diarrhea (gastroenteritis), feeling like you are spinning (vertigo), weight gain, injection-site reactions (such as redness, swelling, warmth, or itching), and nausea.

IN THE
DAYS AHEAD

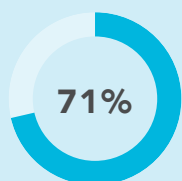
SHE WANTS TO
FOCUS ON DRAWING,
NOT HER DISEASE.

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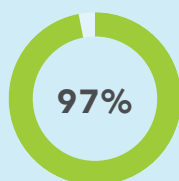
Proven results with ILARIS

Within the first treatment period, ILARIS® provided a complete response from CAPS (MWS):

THE PERCENTAGE OF PATIENTS WHO HAD A COMPLETE RESPONSE:



WEEK 1
n=(25/35)



WEEK 8
(n=34/35)

A "complete response" is a measurement based on lab tests and a doctor's evaluation that the patient's skin disease and disease activity are minimal or better. The evaluation also assesses symptoms such as rash, fatigue, muscle pain, headache or migraine, sore or red eyes, and joint pain.

In a clinical study, of the 15 patients who received 4 doses of ILARIS, none experienced a flare* of their symptoms over an 8-month period.

*A flare was measured by laboratory tests and a doctor's evaluation of the patients' symptoms being mild or worse, or an evaluation of both the patients' symptoms and skin disease being minimal or worse.

IMPORTANT SAFETY INFORMATION (cont)

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

What is Macrophage Activation Syndrome (MAS)?

MAS is a syndrome associated with Still's disease and some other autoinflammatory diseases like Hyperimmunoglobulin D Syndrome (HIDS), also known as Mevalonate Kinase Deficiency (MKD), that can lead to death. Tell your healthcare provider right away if your Adult-Onset Still's Disease (AOSD) 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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IMPORTANT SAFETY INFORMATION (cont)

ILARIS[®] can cause serious side effects, including:

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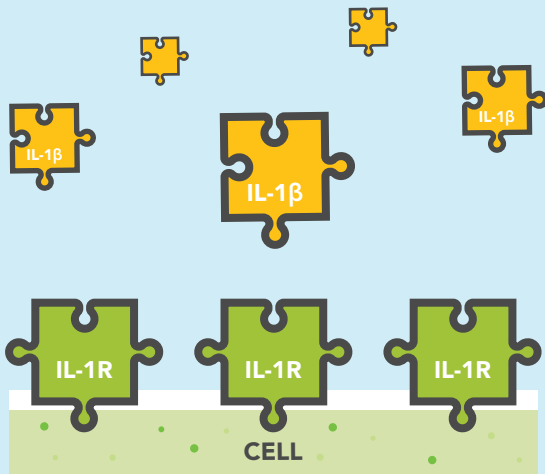
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How ILARIS works

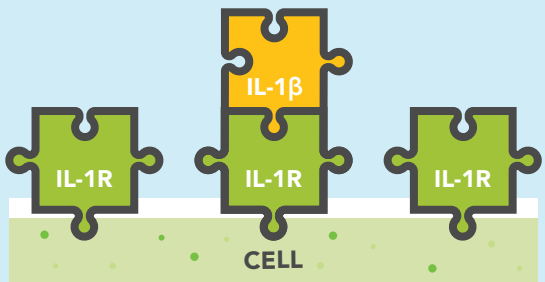
IL-1 β IS A KEY CAUSE OF INFLAMMATION IN CAPS

In patients with CAPS, 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.

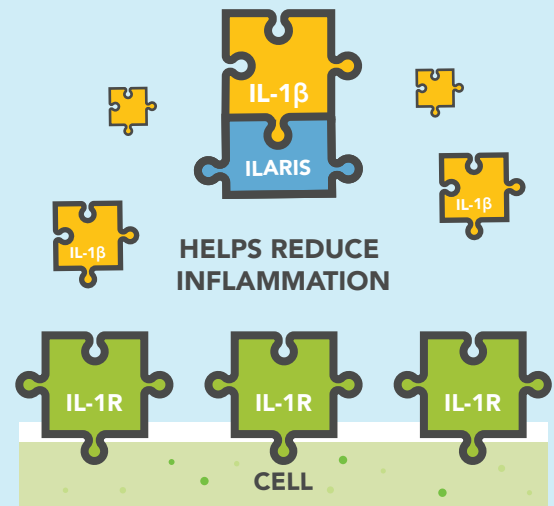
TRIGGERS
INFLAMMATION



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.



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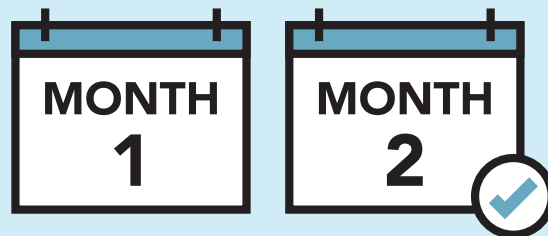
How to take ILARIS



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**ILARIS[®] IS GIVEN ONCE EVERY 8 WEEKS—
JUST 6 OR 7 TREATMENTS A YEAR.**

**A doctor or nurse gives 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 bi-monthly ILARIS injection. See the following page for more information.

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.

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.

Resources to help you or your child

TIPS TO HELP MANAGE SYMPTOMS

Use these quick tips to help manage the symptoms of CAPS.



**DRESS WARMLY,
WEARING EXTRA LAYERS**



SOAK IN A WARM BATH



DRINK WARM BEVERAGES

While these precautions may help you manage the onset of CAPS symptoms, they are not considered to be a treatment for either FCAS or MWS.

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LEARN MORE ABOUT CAPS

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/CAPSResources OR SCAN THE QR CODE WITH YOUR PHONE.



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

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- have symptoms of infection
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