



YOUR FAMILY AND CAPS

(CRYOPYRIN-ASSOCIATED PERIODIC SYNDROMES)

WHAT ARE CAPS?

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

- 1 FAMILIAL COLD AUTOINFLAMMATORY SYNDROME (FCAS)
- 2 MUCKLE-WELLS SYNDROME (MWS)

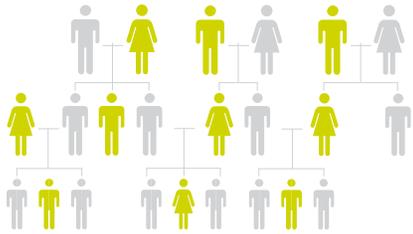
WHO GETS CAPS?



CAPS ARE A GROUP OF RARE DISEASES ESTIMATED TO AFFECT ABOUT

1 IN EVERY MILLION

PEOPLE WORLDWIDE*



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

CAPS are a group of dominant genetic diseases that often run in families.

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

It's important to know that CAPS are **not contagious** and although the disease is not curable, it can be managed with medication.

*Cuisset, L, et al. Genetic Linkage of the Muckle-Wells Syndrome to Chromosome 1q44. Am J Hum Genet. 1999; 65 (5): 1054-59.

COMMON CAPS SYMPTOMS:



FEVER



FATIGUE



HEADACHE OR MIGRAINE



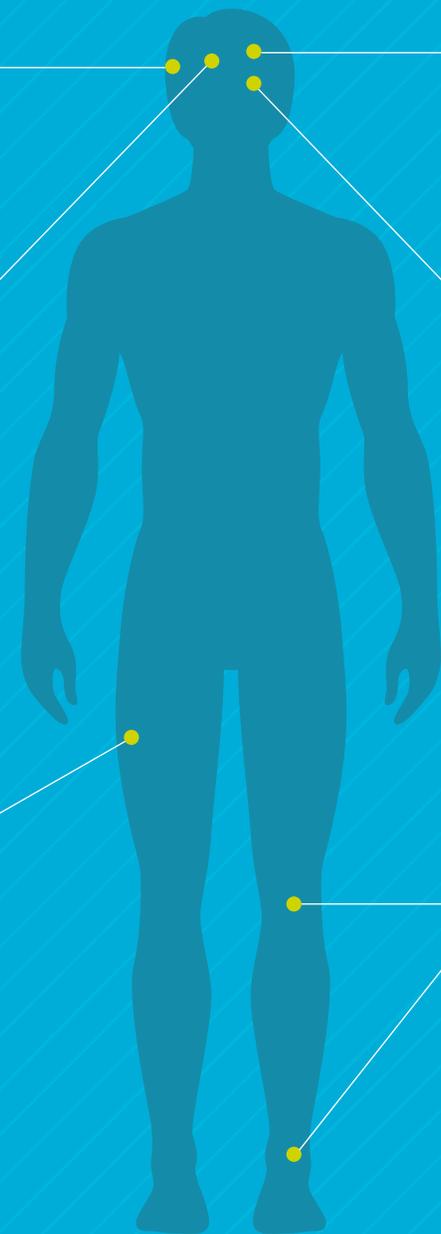
SORE OR RED EYES



HIVE-LIKE RASH



MUSCLE AND/OR JOINT PAIN



DIAGNOSING CAPS CAN BE A CHALLENGE

CAPS can be difficult to diagnose because the symptoms are similar to those of other common conditions. But in CAPS, symptoms are chronic in nature, meaning that they often happen on a daily basis. Because these conditions are so rare, only a few doctors have experience recognizing and/or treating CAPS. CAPS are often misdiagnosed, so getting an accurate diagnosis can be a frustrating process. So some people experience symptoms for many years before getting a diagnosis, while others live with CAPS without ever being diagnosed.

CAPS SYMPTOMS MAY BE TRIGGERED BY:



Exposure to cold



A drop in temperature



Stress



Exercise

...or no clear reason at all.

TIPS TO HELP MANAGE SYMPTOMS



DRESS WARMLY, WEARING EXTRA LAYERS



SOAK IN A WARM BATH



DRINK WARM BEVERAGES

HOW DO I KNOW IF I HAVE CAPS?

If you answer “yes” to the questions below, you should talk to your doctor or schedule an appointment with a rheumatologist or allergist/immunologist to find out if you have CAPS. Bring this booklet with you to your next doctor’s appointment to help you remember your symptoms and details of your family history that you want to discuss.

- 1 Do you experience both of these symptoms on a regular basis, or in response to changes in temperature or environment?

 - Rash on an ongoing basis
 - Fever or chills on an ongoing basis
- 2 In addition to ongoing rash and/or fever/chills, do you frequently have 1 or more of the following?

 - Headache or migraine
 - Fatigue (tiredness)
 - Sore or red eyes
 - Muscle or joint pain
- 3 Has any family member reported similar symptoms or received a diagnosis of CAPS?

 - Yes
 - No

Only a health care professional can diagnose someone with CAPS.

WHAT YOU CAN DO IF YOU SUSPECT YOU MAY HAVE CAPS

1 Learn more about CAPS

There are many resources available to 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

RareConnect

www.rareconnect.org/en/community/caps

Arthritis Foundation

www.arthritis.org

2 Contact your doctor

CAPS is a group of rare diseases that only a doctor can diagnose. Not all doctors have experience with CAPS patients. You may need to see a rheumatologist or allergist/immunologist, someone who specializes in treating conditions like CAPS.

IF YOU'RE DIAGNOSED WITH CAPS, YOUR DOCTOR MAY DECIDE THAT TREATMENT WITH ILARIS IS RIGHT FOR YOU

ILARIS is the first and only treatment approved by the FDA for cryopyrin-associated periodic syndromes, specifically familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS), in adults and children aged 4 years and older. ILARIS is an injection, given every 8 weeks, that addresses a key cause of inflammation and can help manage CAPS symptoms.

For more information about ILARIS, visit www.ILARIS.com.

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 auto-inflammatory 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.

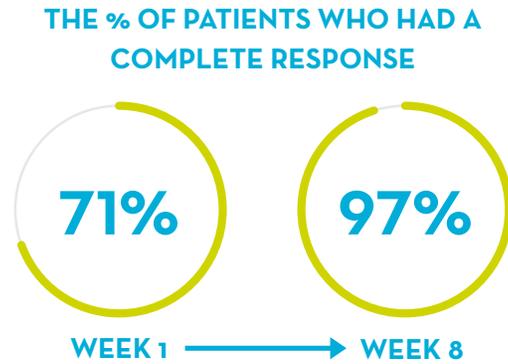
IMPORTANT SAFETY INFORMATION

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

STUDY WITH ILARIS®

In a study of **35 patients** with CAPS:



A “complete response” is a measurement based on lab results 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.

TREATMENT RESULTS WITH ILARIS

Patients had long-lasting relief

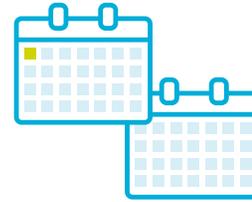


- In the study, **all patients** taking ILARIS experienced long-lasting response regarding their symptoms—**no flare for 24 weeks**
- A “flare” is based upon lab results and by the doctor’s evaluation that disease activity was mild or worse, or disease activity and skin disease were minimal or worse



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

ILARIS is given only once every 8 weeks—just 6 or 7 treatments in a year



- ILARIS is a subcutaneous injection (under the skin) given by a doctor or other health care professional
- ILARIS is available by prescription only

IF YOU’RE DIAGNOSED WITH CAPS AND YOUR DOCTOR DECIDES ILARIS IS RIGHT FOR YOU, YOU MAY BE ELIGIBLE FOR ILARIS COMPANION, INCLUDING CO-PAY ASSISTANCE.

For more information, go to ILARIS.com.

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.

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

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 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

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.

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.

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

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.



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

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 aged 4 years and older who have auto-inflammatory 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.

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 8 weeks for CAPS.

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 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, 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?

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 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.

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