

**Medication Guide**  
**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 4 years of age and older who have auto-inflammatory diseases called Cryopyrin-Associated Syndromes (CAPS), including:
  - Familial Cold Auto-inflammatory Syndrome (FCAS)
  - Muckle-Wells Syndrome (MWS)
- Systemic Juvenile Idiopathic Arthritis (SJIA) in children 2 years of age and older.

It is not known if ILARIS is safe and effective when used to treat SJIA in children under 2 years of age or 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 end of this 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.
- are breastfeeding or planning to breastfeed. It is not known if ILARIS passes into your breast milk. You and your healthcare provider should decide if you will receive ILARIS or breastfeed. You should not do both.

**Tell your healthcare provider about all the medicines you take**, including prescription and nonprescription 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<sup>®</sup> (anakinra), Arcalyst<sup>®</sup> (rilonacept)
- Medicines called Tumor Necrosis Factor (TNF) inhibitors such as Enbrel<sup>®</sup> (etanercept), Humira<sup>®</sup> (adalimumab), Remicade<sup>®</sup> (infliximab), Simponi<sup>®</sup> (golimumab), or Cimzia<sup>®</sup> (certolizimab pegol)
- Medicines that effect enzyme metabolism

Ask your healthcare provider if you are not sure.

### **How will I receive ILARIS?**

- ILARIS is given by your healthcare provider every 8 weeks for CAPS and every 4 weeks for SJIA.

### **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:
  - rash
  - itching and hives

- difficulty breathing or swallowing
- dizziness or feeling faint
- **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 include:**

**When ILARIS is used for the treatment of CAPS:**

- cold symptoms
- diarrhea
- flu (influenza)
- runny nose
- nausea
- headache
- cough
- weight gain
- body aches
- feeling like you are spinning (vertigo)
- injection site reactions (such as redness, swelling, warmth, or itching)

**When ILARIS is used for treatment of the SJIA:**

- cold symptoms
- upper respiratory tract infection
- pneumonia
- runny nose
- sore throat
- urinary tract infection
- nausea, vomiting, and diarrhea (gastroenteritis)
- stomach pain
- injection site reactions

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. Do not use ILARIS for a condition for which it was not prescribed. Do not give ILARIS to other people, even if they have the same condition as you. It may harm them.

This Medication Guide summarizes the most important information about ILARIS. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about ILARIS that was written for health professionals. For more information about ILARIS, call 1-877-452-7471 or visit [www.ILARIS.com](http://www.ILARIS.com).

## **What are the ingredients in ILARIS?**

**Active ingredient:** canakinumab

**Inactive ingredients:** sucrose, L-histidine, L-histidine HCl monohydrate, polysorbate 80, preservative-free sterile water for injection

## **What are CAPS?**

CAPS are a group of illnesses that run in families where patients make too much IL-1 $\beta$ . The IL-1 $\beta$  triggers inflammation. This leads to symptoms such as rash, fever/chills, joint pain, fatigue, and eye pain and redness.

## **What is SJIA?**

SJIA is an autoinflammatory disorder which can be caused by having too much or being too sensitive to certain proteins, including interleukin-1 $\beta$  (IL-1 $\beta$ ), and can lead to symptoms such as fever, rash, headache, fatigue, or painful joints and muscles.

## **What is Macrophage Activation Syndrome (MAS)?**

MAS is a syndrome associated with SJIA that can lead to death. Tell your healthcare provider right away if your 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

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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