

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.

See "**What are possible side effects of ILARIS?**" for more information about side effects.

What is ILARIS?

ILARIS is a prescription medicine injected by your healthcare provider just below the skin (subcutaneous) used to treat:

- The following Periodic Fever Syndromes:
 - Adults and children 4 years of age and older who have auto-inflammatory diseases called Cryopyrin-Associated Periodic Syndromes (CAPS), including:
 - Familial Cold Auto-inflammatory Syndrome (FCAS).
 - Muckle-Wells Syndrome (MWS).
 - Adults and children who have an auto-inflammatory disease called Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS).
 - Adults and children who have an auto-inflammatory disease called Hyperimmunoglobulin D Syndrome (HIDS) [also known as Mevalonate Kinase Deficiency (MKD)].
 - Adults and children who have an auto-inflammatory disease called Familial Mediterranean Fever (FMF).
- Still's disease, including Adult-Onset Still's Disease (AOSD) and Systemic Juvenile Idiopathic Arthritis (SJIA) in children 2 years of age and older.
- Gout flares in adults who:
 - are not able to receive or tolerate treatment with non-steroidal anti-inflammatory drugs (NSAIDS) and colchicine.
 - have not responded to treatment with NSAIDS and colchicine.
 - are not able to receive repeated treatment with steroids.

It is not known if ILARIS is safe and effective when used to treat:

- SJIA in children under 2 years of age.
- CAPS in children under 4 years of age.
- gout flares in children.

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.

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.
- 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.

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.

How should I receive ILARIS?

- ILARIS is given by your healthcare provider as an injection under the skin (subcutaneous injection):
 - every 8 weeks for CAPS.
 - every 4 weeks for TRAPS, HIDS/MKD, FMF, AOSD, and SJIA.
 - as a single dose at the time of a gout flares. If you have a new flare and need another dose of ILARIS, you must wait at least 12 weeks before receiving the next dose.

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
 - headache
 - cough
 - body aches
 - nausea, vomiting, and diarrhea (gastroenteritis)
 - 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 include:

When ILARIS is used for the treatment of CAPS:

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

When ILARIS is used for the treatment of TRAPS, HIDS/MKD, and FMF:

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

When ILARIS is used for the treatment of Still's disease (AOSD and SJIA):

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|-------------------------------------|---------------------------|--|
| • cold symptoms | • runny nose | • nausea, vomiting, and diarrhea (gastroenteritis) |
| • upper respiratory tract infection | • sore throat | • stomach pain |
| • pneumonia | • urinary tract infection | • injection-site reactions (such as redness, swelling, warmth, or itching) |

When ILARIS is used for the treatment of gout flares:

- cold symptoms
- upper respiratory tract infection
- urinary tract infection
- increased levels of triglycerides in the blood
- back pain

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 this Medication Guide. You can ask your healthcare provider or pharmacist for information about ILARIS that was written for health professionals.

What are the ingredients in ILARIS?

Active ingredient: canakinumab.

Inactive ingredients: Solution for Injection: L-histidine, L-histidine HCl monohydrate, mannitol, polysorbate 80, sterile water for injection.

What are Periodic Fever Syndromes?

Periodic Fever Syndromes is the name for several different autoinflammatory 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, such as rash, headache, pain (mostly in the joints, belly, eyes, muscles), fatigue, inflammation of other organs, such as heart, lungs, spleen, and brain.

What is Still's Disease (AOSD and SJIA)?

Still's disease (which is referred to as AOSD in adults and SJIA in children) 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 β), and can lead to symptoms such as fever, rash, headache, feeling very tired (fatigue), or painful joints and muscles.

What is Gout Flare?

A gout flare is caused when a chemical called urate builds-up in the body, and needle-shaped crystals form in and around the joint. These crystals lead to inflammation with excessive production of certain proteins, such as interleukin-1 beta (also called IL-1 β), which in turn can lead to sudden, severe pain, redness, warmth and swelling in a joint.

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 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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For more information about ILARIS, call 1-877-452-7471 or visit www.ILARIS.com.

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

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