Now FDA approved for Adult-Onset Still's Disease (AOSD)

ILARIS is indicated for Still's disease including AOSD and Systemic Juvenile Idiopathic Arthritis (SJIA) in patients 2 years of age and older.

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: Still's disease including Adult-Onset Still's Disease (AOSD) and 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.

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 this brochure, and accompanying Consumer Brief Summary.

ILARIS® may be an option for you

ILARIS is a once-a-month treatment for a rare autoinflammatory condition called Still's disease, which is referred to as Adult-Onset Still's disease (AOSD) in adults and Systemic Juvenile Idiopathic Arthritis (SJIA) in children. It's the only medication FDA approved in the United States to treat both forms of Still's disease.

STILL'S DISEASE CAN BE HARD TO DIAGNOSE:

Patients with autoinflammatory diseases can have systemic (full-body) and arthritic symptoms that are hard to predict. Still's disease can be especially difficult to diagnose because the symptoms are often seen in other diseases.

SYMPTOMS OF STILL'S DISEASE:

ILARIS® (canakinumab) 150 mg subcutaneous injection

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

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.

Proven results with ILARIS®

ILARIS received FDA approval for **SJIA** based on studies that included 190 patients.

FDA approval for **AOSD** was based on established efficacy of ILARIS in SJIA patients and evaluations of clinical data of AOSD and SJIA patients.

ILARIS HELPED PROVIDE FAST SYMPTOM RELIEF IN A STUDY OF PATIENTS WITH SJIA:

3 days after taking their first dose, 100% of patients had no fever

100% fever-free after 3 days

15 days after their first dose, approximately 8 out of 10 patients experienced improvement in fever and painful and/or swollen joints

~8 out of 10 experienced improvement

ILARIS® (canakinumab) 150 mg subcutaneous injection

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

IMPORTANT SAFETY INFORMATION (cont)

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

ILARIS® reduced or stopped corticosteroid use in SJIA*

WITHIN 5 MONTHS:

Almost half of patients (42/92) whose symptoms were controlled appropriately were able to stop taking corticosteroids completely

About 2 out of 3 patients (57/92) whose symptoms were controlled during treatment with ILARIS were able to stop or reduce the use of corticosteroids

*128 patients entered the clinical study taking corticosteroids. 92 of these patients entered a part of the clinical trial to see if they could reduce or stop taking corticosteroids.

ILARIS® (canakinumab) 150 mg subcutaneous injection

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

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

ILARIS® safety considerations

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 medications if you are not sure.

ILARIS® (canakinumab) 150 mg subcutaneous injection

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

IMPORTANT SAFETY INFORMATION (cont)

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
- **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 treatment of Still's disease (AOSD and SJIA) include: cold symptoms, upper respiratory tract infection, pneumonia, runny nose, sore throat, urinary tract infection, nausea, vomiting and diarrhea (gastroenteritis), stomach pain, 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.

ILARIS WAS FDA APPROVED FOR PEOPLE 2 YEARS OF AGE AND OLDER WITH ACTIVE STILL'S DISEASE, INCLUDING AOSD AND SJIA.

In the SJIA clinical studies:

- ILARIS wasn't shown to affect the risk of developing macrophage activation syndrome (MAS), but no conclusion can be made
- No one stopped treatment with ILARIS due to injection-site reactions
- Up to 14% of patients had injection-site reactions; most were mild

Still's disease is an autoinflammatory disease.

AUTOINFLAMMATORY ≠ AUTOIMMUNE

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

Your immune system is your body's natural defense system that protects against "foreign" invaders. Inflammation is just one way your body protects itself against sickness or injury.

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

ILARIS®
(canakinumab)
150 mg subcutaneous injection

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

IMPORTANT SAFETY INFORMATION (cont)

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:

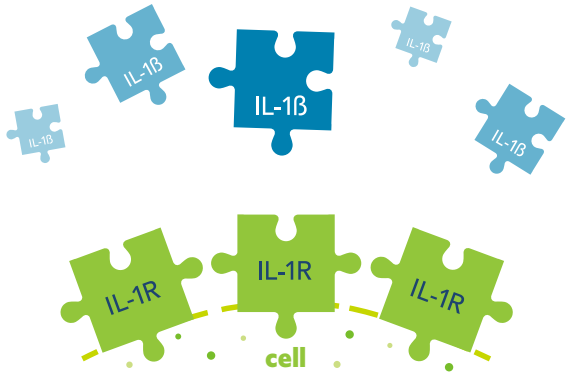
- a fever lasting longer than 3 days
- a cough that does not go away
- redness in one part of your body
- warm feeling or swelling of your skin

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.

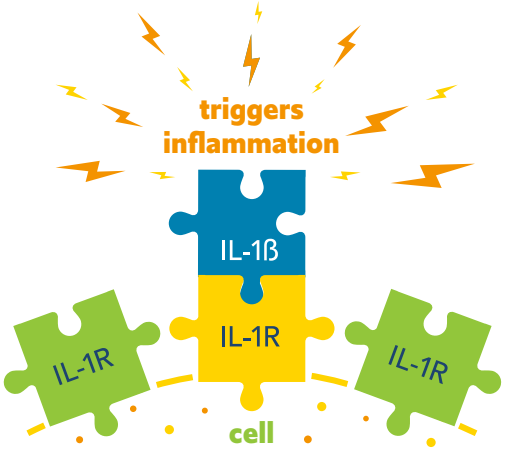
How ILARIS® works

IL-1ß IS A KEY CAUSE OF INFLAMMATION IN STILL'S DISEASE

In patients with Still's disease, the immune system produces too much of or is too sensitive to certain proteins (or cytokines), including interleukin-1 beta (IL-1B), which can lead to inflammation.



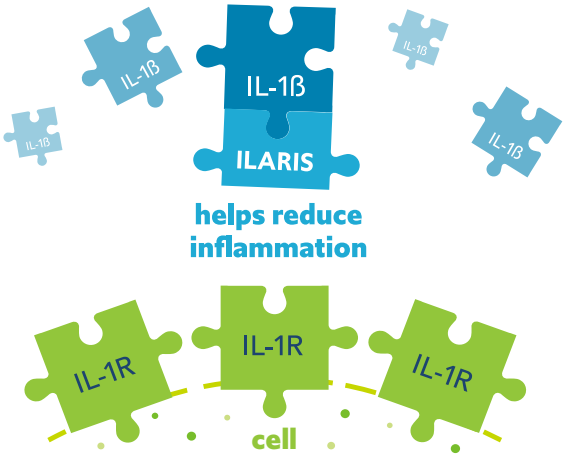
When IL-1ß attaches to interleukin-1 receptors (IL-1R), the immune system triggers inflammation.



ILARIS TARGETS IL-1ß TO HELP REDUCE INFLAMMATION

ILARIS is a biologic medicine designed to target a specific source of inflammation. ILARIS targets IL-1ß.

By attaching to IL-1ß, ILARIS helps to block its interaction with IL-1R. This action helps to stop the immune system from triggering inflammation.



ILARIS® (canakinumab) 150 mg subcutaneous injection

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

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

ILARIS® dosing

1x month

ILARIS has once-monthly dosing. Every 4 weeks, a doctor or nurse will give you a subcutaneous injection (administered right under the skin).

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

ILARIS®
(canakinumab)
150 mg subcutaneous injection

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

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.

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.

Co-pay savings offer*: designed to make ILARIS more affordable for commercially insured patients. Eligible patients pay no more than $30 per month, subject to annual cap.

First Dose Free program*: patients who meet certain requirements may receive a one-time, free dose if necessary.

Insurance assistance: verify health plan benefits, find financial support programs for uninsured and underinsured patients, determine specific prior authorization criteria, and provide support with insurance appeals.

Home Health Nurse Service: at the request of your doctor, a healthcare professional will come to your home, or another convenient location, once a month.

The ILARIS Home Health Nurse:

- administers your once-monthly ILARIS injection
- helps keep you on schedule with dosing each month
- costs nothing for eligible patients
- is available in all 50 states and Puerto Rico

To connect with ILARIS Companion, call **866-972-8315**.

*Limitations apply. Call ILARIS Companion at 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.

IMPORTANT SAFETY INFORMATION (cont)

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

ILARIS® (canakinumab) 150 mg subcutaneous injection

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

Notes

ILARIS®
(canakinumab)
150 mg subcutaneous injection

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

Ask your doctor about ILARIS today.

NOVARTIS

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

ILARIS®
(canakinumab)
150 mg subcutaneous injection

6/20

T-ILA-1390760

ILARIS® (i-LAHR-us)
(canakinumab)
injection for subcutaneous use

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.

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:

- Still's disease including Adult-Onset Still's Disease (AOSD) and Systemic Juvenile Idiopathic Arthritis (SJIA) in children 2 years and older.

It is not known if ILARIS is safe and effective when used to treat SJIA in children under 2 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.

How will I receive ILARIS?

- ILARIS is given by your healthcare provider every 4 weeks for AOSD and 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:
  - 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 Still's disease (AOSD and SJIA) include:

- cold symptoms, upper respiratory tract infection, pneumonia, runny nose, sore throat, urinary tract infection, nausea, vomiting and diarrhea (gastroenteritis), stomach pain, 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 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-1β (IL-1β), and can lead to symptoms such as fever, rash, headache, feeling very tired (fatigue), or painful joints and muscles.

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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