

A CHANCE AT RELIEF ISN'T LUCK. IT'S ILARIS®.

With ILARIS, relief from the arthritic and systemic symptoms of Still's disease may be within reach.

The only FDA-approved medication to treat both forms of Still's disease (SJIA and AOSD)*

ILARIS is indicated for 8 autoinflammatory diseases across Still's disease, periodic fever syndromes (PFS), and gout flares¹

- **Still's disease:** SJIA and AOSD
- **PFS:** FMF, HIDS/MKD, TRAPS, and CAPS (FCAS and MWS)

Not an actual patient. Individual results will vary.

*ILARIS is approved for the treatment of active Still's disease including SJIA and AOSD in patients 2 years of age and older.

AOSD, adult-onset Still's disease; CAPS, cryopyrin-associated periodic syndromes; FCAS, familial cold autoinflammatory syndrome; FMF, familial Mediterranean fever; HIDS, hyperimmunoglobulin D syndrome; MKD, mevalonate kinase deficiency; MWS, Muckle-Wells syndrome; SJIA, systemic juvenile idiopathic arthritis; TRAPS, tumor necrosis factor receptor-associated periodic syndrome.

INDICATIONS

ILARIS® (canakinumab) is an interleukin-1 β blocker indicated for the treatment of the following autoinflammatory Periodic Fever Syndromes:

- Cryopyrin-Associated Periodic Syndromes (CAPS), in adults and pediatric patients 4 years of age and older, including:
 - Familial Cold Autoinflammatory Syndrome (FCAS)
 - Muckle-Wells Syndrome (MWS)
- Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) in adult and pediatric patients
- Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) in adult and pediatric patients
- Familial Mediterranean Fever (FMF) in adult and pediatric patients

ILARIS is indicated for the treatment of active Still's disease, including Adult-Onset Still's Disease (AOSD) and Systemic Juvenile Idiopathic Arthritis (SJIA) in patients 2 years of age and older.

ILARIS is indicated for the symptomatic treatment of adult patients with gout flares in whom nonsteroidal anti-inflammatory drugs (NSAIDs) and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

ILARIS is contraindicated in patients with confirmed hypersensitivity to canakinumab or to any of the excipients.

Please see additional Important Safety Information throughout and full Prescribing Information, including Medication Guide, for ILARIS.

ILARIS®
(canakinumab)
150 mg subcutaneous injection

Fever, rash, and arthritis/arthralgia are the most common symptoms of Still's disease^{2,3}

In patients **less than 16 years of age**, Still's disease is called **SJIA** (typical age of onset is 1 to 5 years old)²⁻⁴

SJIA ²	
Fever	<ul style="list-style-type: none">Occurs daily or twice dailyTemperature may spike to ≥39 °C (≥102.2 °F) with a return to normal or to below baseline temperature
Rash	<div></div> <ul style="list-style-type: none">Transient, salmon-pink colored, macular or maculopapularTypically found on the trunk, neck, and proximal extremities
Arthritis/ Arthralgia	<ul style="list-style-type: none">Can range from oligoarticular to polyarticular patternsPrimarily affects wrists, knees, and ankles

Rash image credit: Reproduced with permission from Gabriella Giancane et al. IL-1 Inhibition in Systemic Juvenile Idiopathic Arthritis. *Front Pharmacol.* 2016;7:467. Figure 1.


IMPORTANT SAFETY INFORMATION (cont)
WARNINGS AND PRECAUTIONS

Serious Infections

ILARIS has been associated with an increased risk of serious infections. Exercise caution when administering ILARIS to patients with infections, a history of recurring infections or underlying conditions, which may predispose them to infections. Avoid administering ILARIS to patients during an active infection requiring medical intervention. Discontinue ILARIS if a patient develops a serious infection.

SJIA and AOSD, which often present similarly, are the juvenile and adult forms of Still's disease²⁻⁵

In patients **16 years of age and older**, Still's disease is called **AOSD** (typical age of onset is 16 to 35 years old)²⁻⁵

AOSD ^{2,3}	
Fever	<ul style="list-style-type: none">Occurs daily or twice daily, lasting <4 hoursTemperature can spike to ≥39 °C (≥102.2 °F)
Rash	<div></div> <ul style="list-style-type: none">Evanescent, salmon-pink colored, maculopapularTypically found on the trunk and proximal extremities
Arthritis/ Arthralgia	<ul style="list-style-type: none">Arthritis may be symmetrical with most developing polyarthritis with fever spikesPrimarily affects wrists, knees, and ankles

Rash image credit: Reproduced with permission from DermNetNZ.org.

Overlapping features and symptoms with other conditions, such as autoimmune diseases, may lead to a **delay in diagnosis or a misdiagnosis.**^{2,3}

Please see additional Important Safety Information throughout and **full Prescribing Information, including Medication Guide, for ILARIS.**



Despite progress in understanding Still's disease, achieving treatment goals may be challenging³

Treatment goals for Still's disease include^{2,6,7}:

Remission across arthritic and systemic manifestations

No long-term steroid use

Prevention of future complications and irreversible disability

Long-term steroid use and the long-term effects of Still's disease can negatively impact patients⁸



Consequences of long-term steroid use

- **Approximately 40%** of patients with AOSD, the adult form of Still's disease, are dependent on steroids, exposing them to serious side effects⁹



Long-term systemic complications

- Uncontrolled systemic inflammation from Still's disease may lead to life-threatening complications and chronic disabilities⁹
- **Up to 14%** of adult patients with Still's disease experience macrophage activation syndrome (MAS), which is often associated with death^{10,11}
- Other complications may include: joint erosion, cardiopulmonary disease, and, in rare cases, disseminated intravascular coagulation and end-organ damage to the liver and kidneys^{10,11}

IMPORTANT SAFETY INFORMATION (cont) WARNINGS AND PRECAUTIONS (cont)

Serious Infections (cont)

Infections, predominantly of the upper respiratory tract, in some instances serious, have been reported with ILARIS. Generally, the observed infections responded to standard therapy. Isolated cases of unusual or opportunistic infections (eg, aspergillosis, atypical mycobacterial infections, cytomegalovirus, herpes zoster) were reported during ILARIS treatment. A causal relationship of ILARIS to these events cannot be excluded. In clinical trials, ILARIS has not been administered concomitantly with tumor necrosis factor (TNF) inhibitors. An increased incidence of serious infections has been associated with administration of another interleukin-1 (IL-1) blocker in combination with TNF inhibitors. Coadministration of ILARIS with TNF inhibitors is not recommended because this may increase the risk of serious infections.



**The ONLY FDA-approved medication to
treat both forms of Still's disease
(SJIA and AOSD)^{1*}**

*ILARIS is approved for the treatment of active Still's disease including SJIA and AOSD in patients ≥2 years old.¹

IMPORTANT SAFETY INFORMATION (cont) WARNINGS AND PRECAUTIONS (cont)

Serious Infections (cont)

Drugs that affect the immune system by blocking TNF have been associated with an increased risk of new tuberculosis (TB) and reactivation of latent TB. It is possible that use of IL-1 inhibitors, such as ILARIS, increases the risk of reactivation of TB or of opportunistic infections.

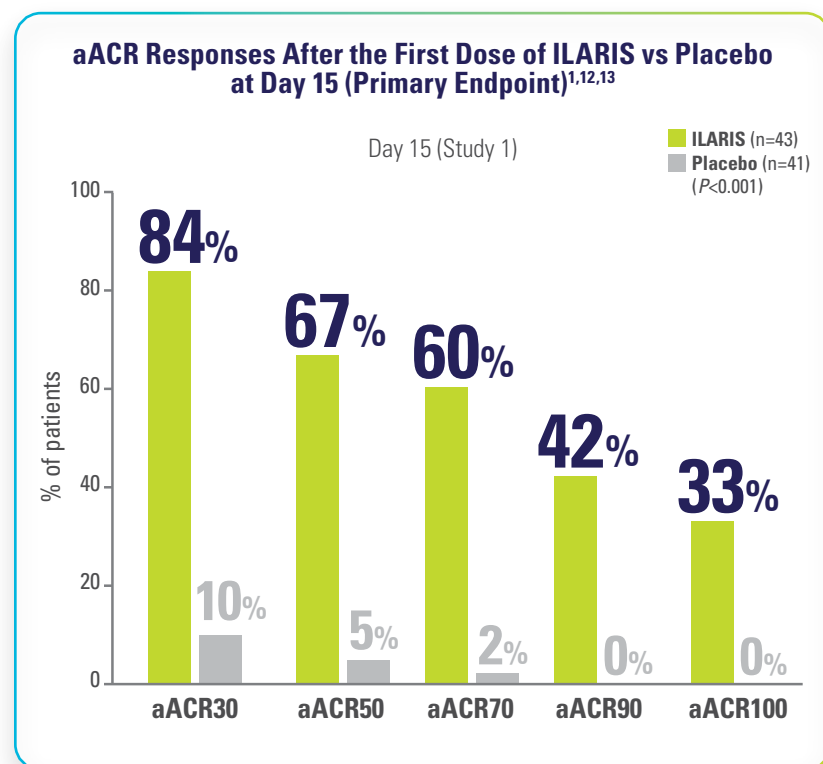
Prior to initiating immunomodulatory therapies, including ILARIS, evaluate patients for active and latent TB infection. Appropriate screening tests should be performed in all patients. ILARIS has not been studied in patients with a positive TB screen, and the safety of ILARIS in individuals with latent TB infection is unknown. Treat patients testing positive in TB screening according to standard medical practice prior to therapy with ILARIS. Instruct patients to seek medical advice if signs, symptoms, or high risk exposure suggestive of TB (eg, persistent cough, weight loss, subfebrile temperature) appear during or after ILARIS therapy. Healthcare providers should follow current CDC guidelines both to evaluate for and to treat possible latent TB infections before initiating therapy with ILARIS.

**Please see additional Important Safety Information
throughout and full Prescribing Information, including
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ILARIS
(canakinumab)
150 mg subcutaneous injection

Rapid relief isn't luck—it's ILARIS

Rapid aACR responses* across arthritic and systemic manifestations within 15 days^{1,12,13}



SJIA Study 1 Design^{1,12}

A randomized, double-blind, placebo-controlled study in 84 patients with SJIA assessed the efficacy of a single subcutaneous dose of ILARIS (4 mg/kg) vs placebo over 29 days. **The primary endpoint was aACR30 at Day 15.**

***aACR response:** Percentage improvement (at least 30%, 50%, 70%, 90%, 100%) from baseline in at least 3 of the 6 pediatric ACR core outcome components along with the absence of fever ($\leq 38^{\circ}\text{C}$ in the preceding 7 days) and worsening of $>30\%$ in no more than 1 of the remaining components. The disease activity components include CRP level, number of joints with active arthritis, number of joints with limited range of motion, physician's global assessment of disease activity, parent's or patient's global assessment of patient's overall well-being, and functional ability (CHAQ-DI).^{12,13}

aACR, adapted JIA American College of Rheumatology; CHAQ-DI, Child Health Assessment Questionnaire-Disability Index; CRP, C-reactive protein.

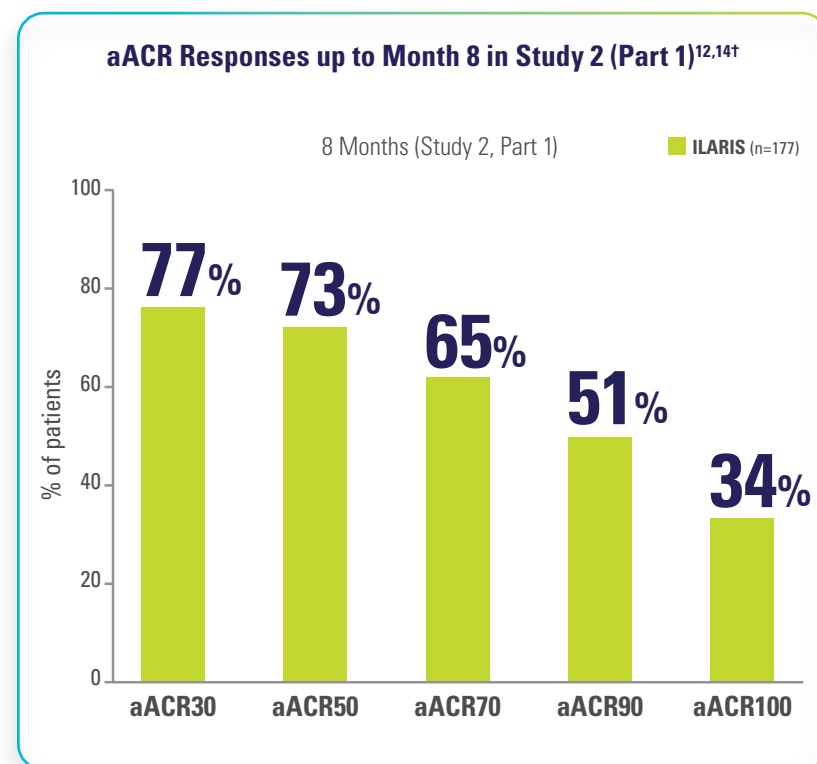
IMPORTANT SAFETY INFORMATION (cont) WARNINGS AND PRECAUTIONS (cont)

Immunosuppression

The impact of treatment with anti-IL-1 therapy on the development of malignancies is not known. However, treatment with immunosuppressants, including ILARIS, may result in an increase in the risk of malignancies.

Choose long-term relief with ILARIS

Long-term aACR responses* across arthritic and systemic manifestations up to Month 8^{12,14†}



SJIA Study 2 Design (Part 1)^{1,12,14}

An open-label steroid-tapering phase in which 177 patients were treated with a 4-mg/kg subcutaneous dose of ILARIS every 4 weeks for 12 to 32 weeks. Patients receiving concomitant corticosteroids at the beginning of the study were allowed to taper corticosteroid use from Week 9 through Week 28 if they achieved minimum aACR50.

- **The primary endpoint was corticosteroid tapering in at least 25% of patients being treated with corticosteroids (45% [57/128] were able to taper their dose of corticosteroids by the end of the steroid-tapering period in Study 2 [Part 1])**

[†]End of Study 2 (Part 1) results shown are based on patients' last available assessments.¹⁴

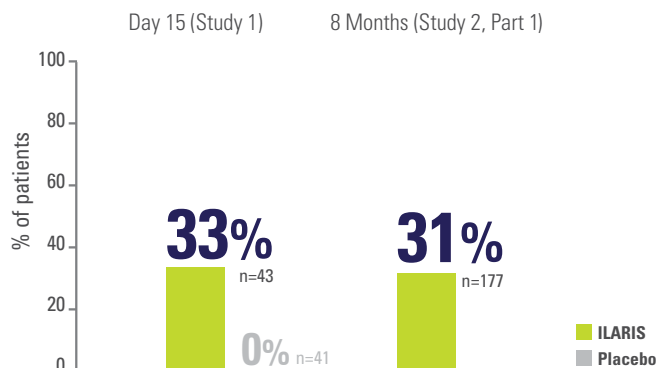
Please see additional Important Safety Information throughout and full Prescribing Information, including Medication Guide, for ILARIS.

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In an exploratory post hoc analysis, remission* was observed in 33% of patients taking ILARIS^{12,13,15}

Rapid disease inactivity* was observed at Day 15 and long-term (up to 8 months) disease inactivity was seen on ILARIS^{12,13,15}

aACR Responses up to Month 8 in Study 2 (Part 1)^{12,13,15}



For 1 in 3 patients, disease inactivity* was observed after 15 days of starting treatment with ILARIS (vs none with placebo)^{12,13,15}

Analysis is exploratory and has not been adjusted for multiple comparisons. No conclusions can be drawn.

Patients were evaluated for inactive disease (ie, absence of active arthritis, fever, and signs or symptoms of SJIA; normal CRP level; and physician's global assessment of disease activity of ≤ 10 mm).^{12,13,15}

***Remission (inactive disease):** Absence of active arthritis, fever, rheumatoid rash, serositis, splenomegaly, hepatomegaly, or generalized lymphadenopathy attributable to SJIA; normal ESR or CRP; physician's global assessment of disease activity indicating no disease activity. *P* values were not determined for comparison regarding inactive disease.^{12,13,15}

ESR, erythrocyte sedimentation rate.

IMPORTANT SAFETY INFORMATION (cont)

WARNINGS AND PRECAUTIONS (cont)

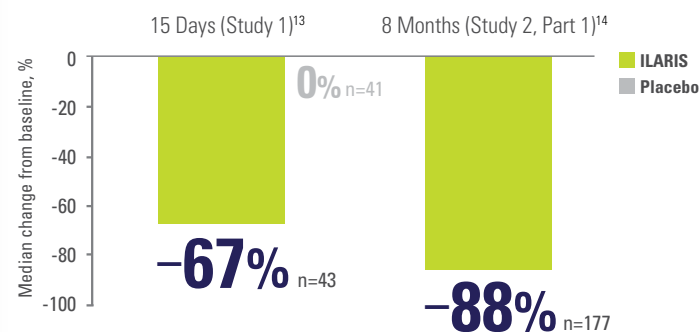
Hypersensitivity Reactions

Hypersensitivity reactions have been reported with ILARIS. During clinical trials, no anaphylactic reactions attributable to treatment with canakinumab have been reported. It should be recognized that symptoms of the underlying disease being treated may be similar to symptoms of hypersensitivity. Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), characterized by serious skin eruptions, has been reported in patients with autoinflammatory conditions treated with ILARIS. If a severe hypersensitivity reaction occurs, immediately discontinue ILARIS; treat promptly and monitor until signs and symptoms resolve.

ILARIS delivered rapid relief from arthritic manifestations that improved over time^{13,14}

Within 15 days and up to 8 months, ILARIS reduced the number of active arthritic joints^{13,14}

Median Reduction in Number of Active Arthritic Joints in Study 1 and Study 2 (Part 1)

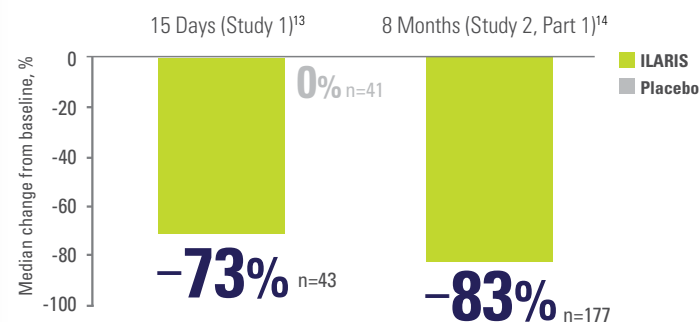


Median number of active arthritic joints at baseline¹²:

- Trial 1: Placebo, 7.0; ILARIS, 10.0
- Trial 2: ILARIS, 10.0

Within 15 days and up to 8 months, ILARIS reduced the number of joints with limited range of motion^{13,14}

Median Reduction in Number of Joints With Limited Range of Motion in Study 1 and Study 2 (Part 1)



Median number of joints with limited range at baseline¹²:

- Trial 1: Placebo, 6.0; ILARIS, 8.0
- Trial 2: ILARIS, 9.0

Results for the systemic and arthritic components of the pediatric aACR core set were consistent with the overall aACR response results.¹

The analysis of the aACR components have not been adjusted for multiple comparisons. No conclusions of statistical or clinical significance can be drawn.

See SJIA Study 1 Design and SJIA Study 2 Design (Part 1) on pages 6 and 7.

Please see additional Important Safety Information throughout and full Prescribing Information, including Medication Guide, for ILARIS.

ILARIS
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ILARIS decreased steroid use and significantly reduced the risk of flare^{1*}

Of the 92 patients who attempted to taper their corticosteroids[†]:
62% OF PATIENTS SUCCESSFULLY TAPERED[‡]
THEIR STEROID USE (n/N=57/92) AND 46%
DISCONTINUED USE ENTIRELY (n/N=42/92)¹

SJIA Study 2 Design (Part 1)^{1,12,14}

An open-label steroid-tapering phase in which 177 patients were treated with a 4-mg/kg subcutaneous dose of ILARIS every 4 weeks for 12 to 32 weeks. Patients receiving concomitant corticosteroids at the beginning of the study were allowed to taper corticosteroid use from Week 9 through Week 28 if they achieved minimum aACR50.

- The primary endpoint was corticosteroid tapering in at least 25% of patients being treated with corticosteroids (45% [57/128] were able to taper their dose of corticosteroids by the end of the steroid-tapering period in Study 2 [Part 1])

***Flare:** Worsening of $\geq 30\%$ in at least 3 of the 6 core aACR response variables combined with improvement of $\geq 30\%$ in no more than 1 of the 6 variables, or reappearance of fever not due to infections for at least 2 consecutive days.¹

[†]92 of the total 128 patients taking corticosteroids who entered the open-label portion of Study 2.¹

[‡]**Successful corticosteroid tapering:** Oral prednisone (or equivalent) dose reduction from >0.8 to ≤ 0.5 mg/kg/day, or from ≥ 0.5 and ≤ 0.8 mg/kg/day by at least 0.3 mg/kg/day, or from any initial dose to ≤ 0.2 mg/kg/day, while maintaining a minimum aACR30 response.¹⁴

IMPORTANT SAFETY INFORMATION (cont) WARNINGS AND PRECAUTIONS (cont)

Immunizations

Avoid administration of live vaccines concurrently with ILARIS. Update all recommended vaccinations prior to initiation of therapy with ILARIS. In addition, because ILARIS may interfere with normal immune response to new antigens, vaccinations may not be effective in patients receiving ILARIS.

Canakinumab, like other monoclonal antibodies, is actively transported across the placenta mainly during the third trimester of pregnancy and may cause immunosuppression in the *in utero* exposed infant. The risks and benefits should be considered prior to administering live vaccines to infants who were exposed to ILARIS *in utero* for at least 4 to 12 months following the mother's last dose of ILARIS.



ILARIS DEMONSTRATED A 64% RELATIVE REDUCTION IN FLARE RISK COMPARED WITH PLACEBO FOR DISEASE CONTROL¹

- The study was ended after 37 flare events occurred. Median duration with ILARIS was 221.5 days vs 163.5 days with placebo. Hazard ratio was 0.36 (95% CI, 0.17-0.75)^{1,12,14}

SJIA Study 2 Design (Part 2)^{1,12,14}

A double-blind withdrawal trial in which patients from Study 2 (Part 1) who achieved and sustained aACR30 or above in Part 1 and were not taking corticosteroids or who had undergone successful corticosteroid tapering were subsequently randomized to ILARIS 4 mg/kg (n=50) or placebo (n=50) every 4 weeks.

- The primary endpoint was time to flare event with ILARIS vs placebo

The efficacy of ILARIS in adults with AOSD is based on the pharmacokinetic exposure and extrapolation of the established efficacy of ILARIS in SJIA patients. Efficacy of ILARIS was also assessed in a randomized, double-blind, placebo-controlled study that enrolled 36 patients (22 to 70 years old) diagnosed with AOSD. The efficacy data were generally consistent with the results of a pooled efficacy analysis of SJIA patients.¹

IMPORTANT SAFETY INFORMATION (cont) WARNINGS AND PRECAUTIONS (cont)

Macrophage Activation Syndrome

Macrophage Activation Syndrome (MAS) is a known, life-threatening disorder that may develop in patients with rheumatic conditions, in particular Still's disease, and should be aggressively treated. Physicians should be attentive to symptoms of infection or worsening of Still's disease as these are known triggers for MAS. Eleven cases of MAS were observed in 201 SJIA patients treated with canakinumab in clinical trials. Based on the clinical trial experience, ILARIS does not appear to increase the incidence of MAS in Still's disease patients, but no definitive conclusion can be made.

ADVERSE REACTIONS

Serious adverse reactions reported with ILARIS in the CAPS clinical trials included infections and vertigo. The most common adverse reactions greater than 10% associated with ILARIS treatment in CAPS patients were nasopharyngitis, diarrhea, influenza, rhinitis, headache, nausea, bronchitis, gastroenteritis, pharyngitis, weight increased, musculoskeletal pain, and vertigo.

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Consistent safety profile of ILARIS in patients aged 2 years and older¹

Pivotal Studies	SJIA Study 1	
	ILARIS (n=43)	Placebo (n=41)
All infections, %*	30	12
Exposure-adjusted incidence rate per 100 patient-days	1.26	1.37
Abdominal pain (upper), %	7	2
Exposure-adjusted incidence rate per 100 patient-days	0.25	0.23
Mild injection site reaction, %	0	7
Moderate injection site reaction, %	0	0

Pivotal Studies	SJIA Study 2		
	Corticosteroid-tapering phase	ILARIS withdrawal phase	
	ILARIS (n=177)	ILARIS (n=50)	Placebo (n=50)
All infections, %*	55	54	38
Exposure-adjusted incidence rate per 100 patient-days	0.91	0.59	0.63
Abdominal pain (upper), %	14	16	12
Exposure-adjusted incidence rate per 100 patient-days	0.16	0.15	0.08
Mild injection site reaction, %	11	12	4
Moderate injection site reaction, %	1	2	0

ILARIS did not appear to increase the incidence of MAS¹

Eleven cases of MAS were observed in 201 patients with SJIA treated with ILARIS in clinical trials. Based on the clinical trial experience, ILARIS does not appear to increase the incidence of MAS in patients with Still's disease, but no definitive conclusions can be made.

MAS is a known life-threatening disorder that may develop in patients with rheumatic conditions, in particular Still's disease, and should be aggressively treated.

Additional safety information¹

- ILARIS has been associated with an increased risk of serious infections. Infections, predominantly of the upper respiratory tract, in some instances serious, have been reported with ILARIS
- Generally, the observed infections in ILARIS clinical trials responded to standard therapy. Isolated cases of unusual or opportunistic infections (eg, aspergillosis, atypical mycobacterial infections, cytomegalovirus, herpes zoster) were reported during ILARIS treatment. A causal relationship of ILARIS to these events cannot be excluded
- Serious infections (eg, pneumonia, varicella, gastroenteritis, measles, sepsis, otitis media, sinusitis, adenovirus, lymph node abscess, pharyngitis) were observed in approximately 4% to 5% (0.02 to 0.17 per 100 patient-days) of patients receiving ILARIS in pivotal studies
- No injection site reactions led to study discontinuation
- No anaphylactic reactions attributable to treatment with canakinumab were reported

The safety profile of ILARIS in patients with AOSD in a randomized, double-blind, placebo-controlled study in 36 adults, aged 22 to 70 years old, was similar to what was observed in patients with SJIA.¹

ILARIS is the only FDA-approved once-monthly treatment in Still's disease¹

- For patients ≥7.5 kg, the recommended weight-based dose of ILARIS for patients with Still's disease is 4 mg/kg (with a maximum of 300 mg) every 4 weeks¹
- ILARIS is given subcutaneously by a health care professional and can be administered in office, patients' homes, or at another location outside of the physician's office¹

Refer to the full Prescribing Information for detailed preparation and administration instructions.

*The most commonly reported infections were nasopharyngitis and (viral) upper respiratory tract infection. Other infections included pneumonia, rhinitis, pharyngitis, tonsillitis, sinusitis, urinary tract infection, gastroenteritis, and viral infections.¹

Please see additional Important Safety Information throughout and full Prescribing Information, including Medication Guide, for ILARIS.



Dedicated and dependable support with ILARIS Companion



ILARIS START FORM

Physician submits form to initiate treatment and patient support services



BENEFITS INVESTIGATION*

Verifies health care plan benefits and provides reimbursement policies for ILARIS



COVERAGE REVIEW AND SUPPORT

Identifies financial support programs for uninsured and underinsured patients



PRIOR AUTHORIZATION (PA) SUPPORT†

Assists in identifying plan-specific PA criteria, if required



APPEALS SUPPORT‡

Provides support with insurance appeals



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
- Patients who are insured through federal or state programs are not eligible



ILARIS Free Trial Offer (FTO) Program§

- Free Trial Offer for ILARIS® (canakinumab) is good for one (1) starter dose of ILARIS at no cost for new patients with valid prescription regardless of insurance. For one-time use only
- Sign up using the Free Trial Offer request form to start ILARIS if the patient has an urgent medical need



SPECIALTY PHARMACY OUTREACH

Works with a patient's specialty pharmacy on patient follow-up



PRODUCT DELIVERY SUPPORT

Works with a health care plan's preferred specialty pharmacy to support coordination and delivery of ILARIS to the patient's home or physician's office



HOME HEALTH NURSE SERVICE

Patients can have their injections administered in their homes or at a location other than the physician's office.

- Available in all 50 US states and Puerto Rico
- Requesting physician will receive a visit confirmation

Increased access can help elevate patient care¹⁶

HIGH PA APPROVAL RATE

≈ **90%** of PA requests are approved¹⁶

ILARIS SHIPMENT TIME

12 days is the median time to ship ILARIS to patients¹⁶

If you have questions about services, contact a program representative at

1-866-972-8315

Monday to Friday, 9 AM to 6 PM ET

Program services are available after the clinical decision to prescribe ILARIS has been made.

*Allows patients to learn about the coverage and cost of ILARIS.

†Information provided in support of a PA must be based on the physician's clinical judgment and forms must be completed by the physician/office staff.

‡Limitations apply. See Program Terms and Conditions on the ILARIS Start Form available at www.ilarishcp.com/access. 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.

§See Program Terms and Conditions on ILARIS Free Trial Offer Form available at www.ilarishcp.com/access. This offer is only valid to new patients starting on ILARIS for an FDA approved indication. Novartis reserves the right to rescind revoke or amend this program without notice.

IMPORTANT SAFETY INFORMATION (cont) ADVERSE REACTIONS (cont)

The most common adverse reactions greater than or equal to 10% reported by patients with TRAPS, HIDS/MKD, and FMF treated with ILARIS were injection site reactions and nasopharyngitis.

The most common adverse drug reactions greater than 10% associated with ILARIS treatment in SJIA patients were infections (nasopharyngitis and upper respiratory tract infections), abdominal pain, and injection site reactions.

The most common adverse reactions greater than 2% reported by adult patients with gout flares treated with ILARIS in clinical trials were nasopharyngitis, upper respiratory tract infections, urinary tract infections, hypertriglyceridemia, and back pain.

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ILARIS Companion provides dedicated and dependable support. Contact a program representative at **1-866-972-8315**. For more information, visit **www.ILARISHCP.com**

*ILARIS is approved for the treatment of active Still's disease including SJIA and AOSD in patients 2 years of age and older.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

ILARIS is contraindicated in patients with confirmed hypersensitivity to canakinumab or to any of the excipients.

Please see additional Important Safety Information throughout and full Prescribing Information, including Medication Guide, for ILARIS.

References: **1.** Ilaris. Prescribing information. Novartis Pharmaceuticals Corp. **2.** Lee JJY, Schneider R. Systemic juvenile idiopathic arthritis. *Pediatr Clin N Am*. 2018;65(4):691-709. doi:10.1016/j.pcl.2018.04.005 **3.** Efthimiou P, Paik PK, Bielory L. Diagnosis and management of adult onset Still's disease. *Ann Rheum Dis*. 2006;65(5):564-572. doi:10.1136/ard.2005.042143 **4.** Jamilloux Y, Gerfaud-Valentin M, Martinon F, Belot A, Henry T, Sève P. Pathogenesis of adult-onset Still's disease: new insights from the juvenile counterpart. *Immunol Res*. 2015;61(1-2):53-62. doi:10.1007/s12026-014-8561-9 **5.** Rossi-Semerano L, Koné-Paut I. Is Still's disease an autoinflammatory syndrome? *Int J Inflam*. 2012;2012:480373. doi:10.1155/2012/480373 **6.** Tomaras S, Goetzke CC, Kallinich T, Feist E. Adult-onset Still's disease: clinical aspects and therapeutic approach. *J Clin Med*. 2021;10(4):733. doi:10.3390/jcm10040733 **7.** Macovei LA, Burlui A, Bratoiu I, et al. Adult-onset Still's disease—a complex disease, a challenging treatment. *Int J Mol Sci*. 2022;23(21):12810. doi:10.3390/ijms232112810 **8.** Ma Y, Meng J, Jia J, et al. Current and emerging biological therapy in adult-onset Still's disease. *Rheumatology (Oxford)*. 2021;60(9):3986-4000. doi:10.1093/rheumatology/keab485 **9.** Gerfaud-Valentin M, Jamilloux Y, Iwaz J, Sève P. Adult-onset Still's disease. *Autoimmun Rev*. 2014;13:708-722. **10.** Efthimiou P, Kontzias A, Hur P, Rodha K, Ramakrishna GS, Nakasato P. Adult-onset Still's disease in focus: clinical manifestations, diagnosis, treatment, and unmet needs in the era of targeted therapies. *Semin Arthritis Rheum*. 2021;51(4):858-874. doi:10.1016/j.semarthrit.2021.06.004 **11.** Efthimiou P, Kadavath S, Mehta B. Life-threatening complications of adult-onset Still's disease. *Clin Rheumatol*. 2014;33(3):305-314. doi:10.1007/s10067-014-2487-4 **12.** Ruperto N, Brunner HI, Quartier P, et al; PRINTo; PRCsG. Two randomized trials of canakinumab in systemic juvenile idiopathic arthritis. *N Engl J Med*. 2012;367(25):2396-2406. doi:10.1056/NEJMoa1205099 **13.** Data on file. CACZ885G2305 SJIA Study 1 Clinical Study Report. Novartis Pharmaceuticals Corp; 2011. **14.** Data on file. CACZ885G2301 SJIA Study 2 Clinical Study Report. Novartis Pharmaceuticals Corp; 2012. **15.** Wallace CA, Ruperto N, Giannini E. Preliminary criteria for clinical remission for select categories of juvenile idiopathic arthritis. *J Rheum*. 2004;31(11):2290-2294. **16.** Data on file. ILARIS Companion CRM Statistics Updates 2023. Novartis Pharmaceuticals Corp; 2023.



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