ILARIS DOSING GUIDE

ILARIS Is Given Subcutaneously by a Health Care Professional[1]		
Dosed According to Body Weight	**Recommended Dose**	**Recommended Titration**
1x PER MONTH IN STILL'S DISEASE: SJIA and AOSD[1]		
≥7.5 kg	4 mg/kg (with a maximum of 300 mg) every 4 weeks	–
1x PER MONTH IN PFS: FMF, HIDS/MKD, and TRAPS[1]		
≤40 kg	2 mg/kg every 4 weeks	Dose can be increased to 4 mg/kg every 4 weeks*
>40 kg	150 mg every 4 weeks	Dose can be increased to 300 mg every 4 weeks*
1x EVERY 2 MONTHS IN PFS: CAPS (FCAS and MWS)[1]		
≥15 kg to ≤40 kg	2 mg/kg every 8 weeks	For pediatric patients, dose can be increased to 3 mg/kg every 8 weeks*
>40 kg	150 mg every 8 weeks	–
FOR A GOUT FLARE[1]		
Dosing for gout flares is not based on body weight	For adult patients, the recommended dose is 150 mg as a single dose at the time of a gout flare	In patients who require re-treatment, there should be an interval of at least 12 weeks before a new dose of ILARIS may be administered

*If clinical response is inadequate.

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; PFS, periodic fever syndromes; SJIA, systemic juvenile idiopathic arthritis; TRAPS, tumor necrosis factor receptor–associated periodic syndrome.

Refer to the full Prescribing Information for Dosage and Administration.

INDICATIONS

ILARIS® (canakinumab) is an interleukin-1β 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

Still's Disease (SJIA and AOSD)

Dosing calculations for patients ≥2 years with a body weight ≥7.5 kg: 4 mg/kg every 4 weeks*

WEIGHT (kg)	DOSE (mg)	VOLUME (mL)	VIAL(S)
7.5	30	0.20	1
10	40	0.27	1
15	60	0.40	1
20	80	0.53	1
25	100	0.67	1
30	120	0.80	1
35	140	0.93	1
40	160	1.07	2
45	180	1.20	2
50	200	1.33	2
55	220	1.47	2
60	240	1.60	2
65	260	1.73	2
70	280	1.87	2
≥75	300	2.00	2

*Maximum dose of 300 mg every 4 weeks.

PFS (FMF, HIDS/MKD, and TRAPS)

Dosing calculations for patients with a body weight ≤40 kg: 2 mg/kg every 4 weeks†

WEIGHT (kg)	DOSE (mg)	VOLUME (mL)	VIAL(S)
15	30	0.20	1
16	32	0.21	1
18	36	0.24	1
20	40	0.27	1
22	44	0.29	1
24	48	0.32	1
26	52	0.35	1
28	56	0.37	1
30	60	0.40	1
32	64	0.43	1
34	68	0.45	1
36	72	0.48	1
38	76	0.51	1

†For patients >40 kg: 150 mg subcutaneously, every 4 weeks. The dose can be increased to 300 mg every 4 weeks if response is not adequate. For patients ≤40 kg: The dose can be increased to 4 mg/kg every 4 weeks if response is not adequate.

Refer to the full Prescribing Information for Dosage and Administration.

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.

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.

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.

Please see additional Important Safety Information throughout and [full Prescribing Information, including Medication Guide, for ILARIS](#).

ILARIS®
(canakinumab)
150 mg subcutaneous injection

PFS: CAPS (FCAS and MWS)

Dosing calculations for patients ≥4 years with a body weight ≥15 kg and <40 kg: 2 mg/kg every 8 weeks*

WEIGHT (kg)	DOSE (mg)	VOLUME (mL)	VIAL(S)
15	30	0.20	1
16	32	0.21	1
18	36	0.24	1
20	40	0.27	1
22	44	0.29	1
24	48	0.32	1
26	52	0.35	1
28	56	0.37	1
30	60	0.40	1
32	64	0.43	1
34	68	0.45	1
36	72	0.48	1
38	76	0.51	1
>40	150	1.00	1

*For pediatric patients, the dose can be increased to 3 mg/kg every 8 weeks if response is not adequate.

Gout Flares in Adults

One 150-mg dose at the time of a gout flare†

†In patients who require re-treatment, there should be an interval of at least 12 weeks before a new dose of ILARIS may be administered.

Each single-dose vial of ILARIS injection delivers 150 mg/mL.

Refer to the full Prescribing Information for Dosage and Administration.

IMPORTANT SAFETY INFORMATION (cont)
WARNINGS AND PRECAUTIONS

Serious Infections (cont)

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.

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.

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.

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.

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

ILARIS®
(canakinumab)
150 mg subcutaneous injection

ILARIS is indicated to treat 8 autoinflammatory diseases across Still's disease, PFS, and gout flares

1x PER MONTH in Still's disease, FMF, HIDS/MKD, and TRAPS

1x EVERY 2 MONTHS in CAPS (including FCAS and MWS)

for a gout flare in adult patients administer a single dose at the time of a gout flare
In patients who require re-treatment, there should be an interval of at least 12 weeks before a new dose of ILARIS may be administered.

ILARIS Companion offers a wide range of services and support, including a home health nurse service.

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**

If you have questions about services, contact a program representative at **1-866-972-8315** Monday to Friday, **9 AM to 6 PM ET**

Refer to the full Prescribing Information for Dosage and Administration.

ILARIS Companion offers dedicated and dependable support for your patients.
Visit www.ILARIShcp.com for the full list of services.

IMPORTANT SAFETY INFORMATION (cont)

WARNINGS AND PRECAUTIONS

Immunizations (cont)

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.

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.

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.

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

Reference: 1. Ilaris. Prescribing information. Novartis Pharmaceuticals Corp.

ILARIS® (canakinumab) 150 mg subcutaneous injection

NOVARTIS

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