ILARIS (canakinumab)

DOSING GUIDE

ILARIS Is Given Subcutaneously by a Health Care Professional and Is Dosed According to Body Weight

Body Weight	Recommended Dose	Recommended Titration
ONCE MONTHLY IN STILL'S DISEASE: SJIA and AOSD[1]		
≥7.5 kg	4 mg/kg (with a maximum of 300 mg) every 4 weeks	–
ONCE MONTHLY 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*
ONCE EVERY 2 MONTHS IN PFS: CAPS (FCAS and MWS)[1]		
≥15 kg to ≤40 kg	2 mg/kg every 8 weeks	Dose can be increased to 3 mg/kg*
>40 kg	150 mg every 8 weeks	–

*If clinical response is inadequate.

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

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.

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

ILARIS® (canakinumab) 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 aged 2 years and older.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION

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

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

ILARIS®
(canakinumab)
150 mg subcutaneous injection

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DOSING GUIDE

Each vial of ILARIS contains a concentration of 150 mg/mL.

Still's Disease (SJIA and AOSD)

Dosing calculations for patients ≥2 years with a body weight ≥7.5 kg, 4 mg/kg

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

PFS (FMF, HIDS/MKD, and TRAPS)

Dosing calculations for patients with a body weight ≤40 kg, 2 mg/kg*

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

*The dose can be increased to 4 mg/kg (300 mg for patients with a body weight >40 kg) if response is not adequate.

CAPS (FCAS and MWS)

Dosing calculations for patients with ≥4 years a body weight 15 kg to 40 kg, 2 mg/kg†

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

†The dose can be increased to 3 mg/kg if response is not adequate.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Serious Infections

ILARIS has been associated with an increased risk of serious infections. Physicians should exercise caution when administering ILARIS to patients with infections, a history of recurring infections or underlying conditions, which may predispose them to infections.

ILARIS should not be administered to patients during an active infection requiring medical intervention. Administration of ILARIS should be discontinued 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, patients should be evaluated 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. Patients testing positive in TB screening should be treated by standard medical practice prior to therapy with ILARIS. All patients should be instructed 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.

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.

IMPORTANT SAFETY INFORMATION

Hypersensitivity

Hypersensitivity reactions have been reported with ILARIS therapy. 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. If a severe hypersensitivity reaction occurs, administration of ILARIS should be discontinued and appropriate therapy initiated.

Immunizations

Live vaccines should not be given concurrently with ILARIS. Prior to initiation of therapy with ILARIS, patients should receive all recommended vaccinations. 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.

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.

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

ILARIS®
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150 mg subcutaneous injection

ILARIS (canakinumab) is the only biologic indicated to treat 7 autoinflammatory diseases across Still's disease and a range of PFS

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

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

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

Home Health Nurse Service

Allows patients to have injections administered in their homes or at another location outside of the physician's office

866-972-8315

If you have questions about services, contact a program representative Monday to Friday, 9 AM to 6 PM ET.

ILARIS companion
Dedicated and dependable support

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

IMPORTANT SAFETY INFORMATION

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.

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

Reference: 1. ILARIS [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2020.

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NOVARTIS

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