XPOSE™ program for ILARIS® (Previously called *ILARIS® CARES*) Enrollment form and prescription

Phone: 1-844-279-7673
Fax: 1-866-872-5771

PATIENT INFORMATION

To be completed by the patient or legal representative (please PRINT)

First name:

Last name:

Address: Apt./Unit:

City: Prov.: Postal code:

Date of birth (DD/MM/YYYY): Sex: ☐ Male ☐ Female

Primary phone: ( ) OK to leave message? ☐ No ☐ Yes

Secondary phone: ( ) OK to leave message? ☐ No ☐ Yes

Was Serum Amyloid A (SAA) testing done? ☐ No ☐ Yes

Do you require a Serum Amyloid A (SAA) sent to your office? ☐ No ☐ Yes

Additional comments:

PRESCRIBER INFORMATION

To be completed by the physician (please PRINT)

First name: Physician stamp here

Last name:

Office address:

City: Prov.: Postal code:

Office contact:

Office phone: ( ) Office fax: ( )

Office e-mail:

Hospital/Clinic:

License number:

PHYSICIAN DECLARATION

The XPOSE™ program ("Program") is sponsored by Novartis Pharmaceuticals Canada Inc. ("Novartis") and currently managed by Innomar Strategies Inc. ("Program Administrator"), an independent third-party contracted by Novartis to administer the Program. The Program includes services regarding ILARIS® ("Novartis medication") and the medical conditions it is used to treat. Novartis reserves the right to modify or terminate the Program at any time without prior notice.

I hereby confirm that I am the healthcare provider of the patient identified on this Enrollment and Consent Form. Furthermore, I confirm that my patient has been prescribed ILARIS® for an approved indication as per approved product monograph, as indicated on this form. I agree to provide background information on the Program to patients prior to their enrollment and I will only provide patient information as part of the Program, where applicable, with the patient's express consent.

I understand that the information I provide to the Program Administrator, including information on this form ("my information"), will be used by the Program Administrator and may be shared with Novartis. The Program Administrator will not share patient identifiable information with Novartis, other than as required for adverse event reporting, but may share de-identified patient data to enable Novartis and/or the Program Administrator to assess and improve patient assistance programs and how it provides products and services to patients and healthcare professionals, or as otherwise permitted by law. I agree that I may be contacted by the Program Administrator for information required for the administration of the Program, by email, phone, fax or otherwise, using the contact information that I have provided above.

I understand that the file containing my information will be maintained at the offices of the Program Administrator. Authorized employees, agents and mandataries of the Program Administrator may have access to my information where necessary in order to render the services or for purposes described in this form. Information collected in connection with the Program may be stored or processed outside of Canada, where it may be subject to the laws of foreign jurisdictions. Information on Novartis' policies and practices regarding privacy, including (i) how to obtain a copy of its privacy policy, (ii) how to request access to, or correction of, my personal information, (iii) how to withdraw my consent, is described in the Patient Consent section of this form.

I acknowledge that adverse events may be reported about my patients who are participating in the Program during the course of their participation in the Program. I understand I may be contacted by Novartis or the Program Administrator to provide follow-up information relating to adverse events. Adverse event reports may need to be forwarded to regulatory authorities in and outside of Canada.

Signature:

Date (DD/MM/YYYY):

OFFICIAL PRESCRIPTION FOR PHARMACY

Rx ILARIS® (canakinumab) for subcutaneous injection (DIN 02344939)

PATIENT DIAGNOSIS AND DOSING INFORMATION:

Diagnosis:

Prescription Type: ☐ Initial Dose Patient's weight: _____ kg

☐ **150 mg dose** (for CAPS patients with body weight greater than 40 kg)

☐ **2 mg/kg dose** (for CAPS patients with body weight between 15 kg and 40 kg): _____ mg

☐ **4 mg/kg dose (up to a maximum of 300 mg)** (for SJIA patients with a body weight greater than 9 kg): _____ mg

PLEASE SEE CHART ON REVERSE PAGE FOR GUIDANCE ON DOSING AND DOSE FREQUENCY, AS WELL AS ADDITIONAL DOSING INFORMATION FROM THE PRODUCT MONOGRAPH.

Prescription Type: ☐ Subsequent Dose

☐ **Second dose** _____ mg ☐ **Second dose** _____ **mg/kg:** _____ mg

Duration of treatment (required supply): _____

Please advise where first injection will take place should your patient qualify to receive ILARIS®.

☐ Nurse home injection service ☐ Specialist's clinic

Please advise: As of _____ injection, you wish to consider home injection.

Name of doctor (if different from above):

Address:

City: Prov.: Postal code:

Phone: ( ) Fax: ( )

PATIENT CONSENT

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I have been given the opportunity to discuss this Program with my healthcare provider. I understand that my participation in the Program is voluntary and if I choose not to participate, this will not impact my medical treatment or insurance coverage eligibility. However, if I do not sign this form, I will not be able to participate in the Program and receive assistance from the Program Administrator, as described above.

I understand the Program Administrator may collect information from, and share information with, my healthcare providers and their staff, including my physician(s), nurse(s) and pharmacist(s), as well as well as healthcare providers employed or retained by the Program Administrator for the purposes of the Program (collectively, "Healthcare Providers"), insurance providers (private or public) as well as other service providers as necessary to provide me with services under this Program or to monitor or audit the services provided by the Program, but will not use my information for any other purpose unless required or permitted by law. The information collected and shared may include information about my contact information, date of birth, insurance coverage, prescription, medical condition and other health information, as well as my information included on this form (collectively, "Personal Information"). I authorize my healthcare provider to provide the Program Administrator with this completed form. I agree I may be contacted by the Program Administrator, Healthcare Providers or others in order to provide me with services under the Program, by email, phone or otherwise using the contact information that I provided. I acknowledge that I am responsible for any charges by my cellular phone provider should I choose to be contacted on my cellular phone for the purposes of the Program.

I understand Novartis may receive de-identified data from this Program, but will not receive my personally identifiable information, except for adverse event reporting purposes to enable Novartis to follow-up with my Healthcare Provider(s). This is necessary for Novartis to maintain the most up to date records as to the safety of its products. Adverse event information may need to be reported to health authorities in and outside of Canada.

If Novartis appoints a new program administrator to replace Innomar Strategies Inc., I agree that my Personal Information may be transferred to the new service provider.

I understand that the Program is not intended to provide medical advice or medical diagnoses. I agree to always seek the advice of my physician or other qualified healthcare provider if I have health concerns, and not to disregard professional medical advice based on information read or conveyed as part of the Program.

I understand the file containing my Personal Information will be maintained at the offices of Innomar Strategies Inc. Authorized employees, agents and mandataries of Innomar Strategies Inc. will have access to my Personal Information as necessary to administer the Program. Personal Information collected in connection with the Program, including any adverse event information collected about me (eg. initials, date of birth, gender, but not name) may be stored or processed outside of Canada, where it may be subject to the laws of foreign jurisdictions. For information about Novartis' privacy policies and practices, I can contact Novartis at the phone number provided below or access a copy of Novartis' privacy policy at http://www.novartis.ca/en/util/privacy.shtml.

I have the right to revoke this consent at any time by contacting the Program, at 1-844-279-7673, or by contacting Novartis at 1-800-363-8883. However, I understand that withdrawing my consent will result in the termination of my enrolment in the Program. Further, the withdrawal of my consent will not have a retroactive effect with respect to information about me already collected and disclosed. I may request access to, or correction of, my Personal Information at any time by contacting the program administrator at Ilaris@innomar-strategies.com.

I hereby confirm that I have read and understood the information provided about the Program included on this XPOSE™ Program Enrollment Form. I have also read and understood the Patient Consent section of this form which describes how my Personal Information will be collected, used or disclosed and I consent to participate in the XPOSE™ program.

Signature of patient or legal representative:

Printed name of patient or legal representative:

Date (DD/MM/YYYY):

DOSING INFORMATION

Indication	Body weight	Initial dose	Frequency
CAPS	>40 kg	150 mg	Every 8 weeks
CAPS	≥15 kg and ≤40 kg	2 mg/kg	Every 8 weeks
SJIA	>9 kg	4 mg/kg (up to max. of 300 mg)	Every 4 weeks

ADDITIONAL DOSING INFORMATION FROM THE PRODUCT MONOGRAPH:†

For CAPS patients in which a satisfactory clinical response (resolution of rash and other generalized inflammatory symptoms) has not been achieved 7 days after the first dose, the dose can be individually adjusted in 150 mg or 2 mg/kg increments **with a minimum of 1 week** observation period for satisfactory treatment response between increases, **to a maximum of 600 mg (body weight >40 kg) or 8 mg/kg (body weight 15–40 kg)**.

If a full treatment response is subsequently achieved, the intensified dose should be maintained and administered every 8 weeks.

ILARIS® is indicated for the ongoing management of Cryopyrin-Associated Periodic Syndromes (CAPS), in adults and children aged 2 years and older, including:

- Familial Cold Autoinflammatory Syndrome (FCAS)/Familial Cold Urticaria (FCU)
- Muckle-Wells Syndrome (MWS)

ILARIS® may also be used in Neonatal-Onset Multisystem Inflammatory Disease (NOMID)/Chronic Infantile Neurological, Cutaneous, Articular Syndrome (CINCA). Clinical data have not confirmed improvement in CNS symptoms in patients with this phenotype.

ILARIS® is indicated for the treatment of active Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged 2 years and older.

Clinical studies of ILARIS® did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

In CAPS, ILARIS® is not recommended for use in children below the age of 2 years due to lack of clinical data. In SJIA, the safety and efficacy of ILARIS® in patients below age of 2 years and with a body weight under 9 kg have not been established.

Consult the Product Monograph at www.novartis.ca/IlarisMonograph for contraindications, warnings, precautions, adverse drug reactions, drug interactions, dosing information, and monitoring and laboratory tests. Product Monograph also available by calling 1-800-363-8883.

† Please refer to the Product Monograph for complete dosing and administration details.

XPOSE™

NOVARTIS

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Member PAAB R&D

Pr ILARIS® (canakinumab) 150 mg subcutaneous injection