

## Helpful ILARIS® tools in the information pack

### For you and your patients

In order to increase understanding of the safe and effective use of ILARIS®, you are provided with the educational materials in addition to a copy of the national Prescribing Information.

The educational materials highlight the following aspects:

#### Important safety information focusing on the safety areas of interest

> See this document

#### ILARIS® Preparation and Injection Guide

> Patient-friendly brochure with dosing instructions and step-by-step visuals demonstrating how to successfully reconstitute and administer ILARIS®

> The ILARIS® Injection Administration Guide should be distributed to CAPS patients where self-administration is permitted to provide guidance on self-injection of ILARIS®

> In the case of an administration error, contact:

Novartis s.r.o., Gemini, budova B  
Na Pankráci 1724/129, 140 00 Praha 4  
Tel: +420 225 775 111, Fax: +420 225 775 222

#### The possibility to include patients in the CAPS Registry, facilitating the collection of long term efficacy and safety data

> See this document

#### ILARIS® Patient Alert Card

> A wallet-sized card that patients must carry with them at all times

> You should complete all the empty fields on the card (patient's name, date of first dose, date of most recent dose and actual dose administered, doctor's name and phone number) before you give the card to your patients

> The card serves as a reminder of the dose used for the patient and includes important safety information that all patients should know about ILARIS® treatment

#### Preparation and administration of ILARIS® for pediatric patients

> ILARIS® Preparation and Injection Guide includes a table with volume and respective dose per weight range according to treatment regimen (i.e. 2 mg/kg, 4 mg/kg and 8 mg/kg)

> The alert card should also include the individual dose to be administered. Administration errors should be reported as mentioned above

#### Closely review the contents provided in the information pack prior to prescribing ILARIS®.

## A healthcare professional's guide to treatment of patients with Cryopyrin-Associated Periodic Syndromes (CAPS) with ILARIS®

#### Indication

ILARIS® is indicated for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) in adults, adolescents, and children aged 2 years and older with body weight of 7.5 kg or above, including:

- Muckle-Wells Syndrome (MWS)
- Neonatal-Onset Multisystem Inflammatory Disease (NOMID)/Chronic Infantile Neurological, Cutaneous, Articular syndrome (CINCA)
- Severe forms of Familial Cold Autoinflammatory Syndrome (FCAS)/Familial Cold Urticaria (FCU), presenting with signs and symptoms beyond cold-induced urticarial skin rash

## EDUKAČNÍ MATERIÁLY

### ILARIS (canakinumab)

### Průvodce pro lékaře pro léčbu pacientů s kryopyrin asociovaným periodickým syndromem (CAPS)

Jakékoli podezření na závažný nebo neočekávaný nežádoucí účinek a jiné skutečnosti závažné pro zdraví léčených osob musí být hlášeno Státnímu ústavu pro kontrolu léčiv.

Ilaris je biologický léčivý přípravek. V hlášení je proto nutné uvést jeho přesný obchodní název (Ilaris) a číslo šarže.

Podrobnosti o hlášení najdete na:

<http://www.sukl.cz/nahlasit-nezadouci-ucinek>

Adresa pro zaslání je Státní ústav pro kontrolu léčiv, oddělení farmakovigilance, Šrobárova 48, Praha 10, 100 41, email: [farmakovigilance@sukl.cz](mailto:farmakovigilance@sukl.cz).

Tato informace může být také hlášena společnosti Novartis na adresu:

Novartis s.r.o., Gemini, budova B  
Na Pankráci 1724/129, 140 00 Praha 4  
tel: +420 225 775 131  
fax: +420 225 775 205  
email: [farmakovigilance.cz@novartis.com](mailto:farmakovigilance.cz@novartis.com)

### Dříve než přípravek ILARIS předepíšete, přečtěte si pečlivě souhrn údajů o přípravku (SPC).

- ▼ Tento léčivý přípravek podléhá dalšímu sledování. To umožní rychlé získání nových informací o bezpečnosti. Žádáme zdravotnické pracovníky, aby hlásili jakákoli podezření na nežádoucí účinky.

## Important safety information

### What you should know before treatment with ILARIS®

The following risks are associated with treatment:

#### Infections, including serious infections and opportunistic infections

- Monitor patients carefully for signs and symptoms of infections during and after treatment with ILARIS®
- 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 initiated or continued in patients during an active infection requiring medical intervention
- Isolated cases of unusual or opportunistic infections have been reported with ILARIS®.
- It is unknown if the use of IL-1 inhibitors such as ILARIS® increases the risk of reactivation of tuberculosis. Before initiation of therapy, all patients must be evaluated for both active and latent tuberculosis infection

#### Malignancies

- Perform annual assessments in ILARIS® patients regarding the presence of malignancies
- Malignancy events have been reported in patients treated with ILARIS® during clinical development. The risk for the development of malignancies with anti-IL-1 therapy is unknown

#### Potential risk of immunogenicity and hypersensitivity reactions

- There is a potential risk of immunogenicity (development of anti-ILARIS® antibodies) that might lead to immune-mediated symptoms including hypersensitivity reactions
- Antibodies against ILARIS® were observed in approximately 1.5% of CAPS patients

#### Vaccinations

- No data are available on the risk of secondary transmission of infection by live (attenuated) vaccines in patients receiving ILARIS®. Therefore, live vaccines should not be given concurrently in patients receiving ILARIS® unless the benefits clearly outweigh the risks
- Prior to initiation of ILARIS® therapy, adult and paediatric patients should receive all recommended vaccinations, as appropriate, including pneumococcal and inactivated influenza vaccines

## Important safety information (continued)

### What you should know before treatment with ILARIS®

#### Neutropenia

- Neutropenia (absolute neutrophil count  $<1.5 \times 10^9/L$ ) has been observed with medicinal products that inhibit IL-1, including ILARIS®
- Treatment with ILARIS® should not be initiated in patients with neutropenia
- It is recommended that neutrophil counts be assessed prior to initiating treatment, *after 1 to 2 months and periodically during treatment with ILARIS® (text in italic: in the EU SmPC)*
- If a patient becomes neutropenic monitor the absolute neutrophil count (ANC) and consider discontinuation of treatment

#### Unknown safety in pregnant and lactating women

- It is not known whether ILARIS® is excreted in human milk.
- Formal studies of the potential effect of ILARIS® on human fertility have not been conducted
- Women who are pregnant or desire to become pregnant should be treated only after a thorough benefit-risk evaluation
- Physicians should discuss the risks regarding the unknown safety of ILARIS® in pregnant and lactating women with patients if they become or plan to become pregnant

#### Injection-site reactions

- There is a potential risk of serious injection site reactions related to ILARIS® administration
- Instructions on proper techniques, especially for self-administration, when the patient is willing to and capable to do so, to minimize the risk

#### Disorders of lipoprotein metabolism

- Monitor patients regularly during treatment for changes in their lipid profiles
- In active-controlled gouty arthritis trials, patients treated with ILARIS® showed increased levels of triglycerides; the clinical significance of this observation is unknown

## Identification and inclusion of CAPS patients into the ILARIS® registry



### The ILARIS® registry provides an opportunity to enroll CAPS patients

The ILARIS® β-CONFIDENT registry (study D2401) is a worldwide database of CAPS patients that will assess long-term safety and treatment outcomes with ILARIS® under local care conditions. The registry is open to register pediatric patients.

By registering your pediatric ILARIS® patients, common characteristics between genotype and phenotype, potential disease modification may be established.

The long-term efficacy and safety data provided by the ILARIS® registry can help inform best practices in CAPS for successful treatment outcomes.

Visit the Novartis registry web site at [www.bconfidentregistry.com](http://www.bconfidentregistry.com) for more information.



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