Helpful tools in the information pack

For you and your patients

In order to increase understanding of the safe and effective use of canakinumab, you are provided with these 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

- There are different versions of the guide giving instructions for use of 'Powder for Solution for Injection' and 'Powder and solvent for solution for injection (injection kit)', respectively. Please refer to the correct version.
- Patient-friendly brochure with dosing instructions and step-by-step visuals demonstrating how to successfully reconstitute and administer canakinumab
- The appropriate version of the ILARIS® Preparation and Injection Guide should be distributed to CAPS patients or their caregivers where self-administration is permitted to provide guidance on self-injection of canakinumab
- The Preparation and Injection Guides include tableswith volume and respective dose per weight range according to treatment regimen (i.e. 2 mg/kg, 4 mg/kg and 8 mg/kg)
- In the case of an administration error, contact:

Novartis s.r.o., Gemini, budova B
Na Pankráci 1724/129
140 00 Praha 4
Tel: 800 40 40 50, Fax: 225 775 205

Patient Reminder Card

- You should complete all the empty fields on the card (patient's name, date of first 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 information that patients should know about their canakinumab treatment

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

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EDUKAČNÍ MATERIÁLY

ILARIS® (canakinumab)

Průvodce pro lékaře pro léčbu pacientů s diagnózou periodického syndromu asociovaného s kryopyrinem (CAPS) ILARISEM® (canakinumab).

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 zasílání je Státní ústav pro kontrolu léčiv, oddělení farmakovigilance, Šrobárova 48, Praha 10, 100 41, e-mail: 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: +420 800 40 40 50
fax: +420 225 775 205
e-mail: 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.

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

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 ras

Important safety information

What you should know before treatment with canakinumab

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 canakinumab
- Exercise caution when administering canakinumab to patients with infections, a history of recurring infections, or underlying conditions which may predispose them to infections
- Canakinumab 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 canakinumab.
- It is unknown if the use of IL-1 inhibitors such as canakinumab 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 canakinumab patients regarding the presence of malignancies
- Malignancy events have been reported in patients treated with canakinumab 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-canakinumab antibodies) that might lead to immune-mediated symptoms including hypersensitivity reactions
- Antibodies against canakinumab 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 canakinumab. Therefore, live vaccines should not be given concurrently in patients receiving canakinumab unless the benefits clearly outweigh the risks
- Prior to initiation of canakinumab therapy, adult and paediatric patients should receive all recommended vaccinations, as appropriate, including pneumococcal and inactivated influenza vaccines

Neutropenia

- Neutropenia (absolute neutrophil count <1.5 x 109/L) has been observed with medicinal products that inhibit IL-1, including canakinumab
- Treatment with canakinumab 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 canakinumab
- 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 canakinumab is excreted in human milk.
- Formal studies of the potential effect of canakinumab 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 canakinumab in pregnant and lactating women with patients if they become or plan to become pregnant

Disorders of lipoprotein metabolism

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