

IMPORTANT INFORMATION

ILARIS[®]
(Canakinumab)

PATIENT CARD

150mg subcutaneous injection

For the treatment of Still's disease, including Adult-Onset Still's Disease (AOSD) and Systemic Juvenile Idiopathic Arthritis (SJIA)

Novartis Pharma AG

CH-4002 Basel

Switzerland

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Before canakinumab treatment

- **Infections:** You should not be treated with canakinumab if you have an active infection requiring medical intervention.
- **Vaccinations:** Talk to your doctor about any vaccinations you may need before starting treatment with canakinumab.

During canakinumab treatment

- **Risk of infections:** Use of canakinumab is associated with an increased risk of infections, including serious infections.

If you develop an infection, your canakinumab treatment might need to be interrupted. Tell your doctor

- immediately if you have a fever lasting longer than 3 days or other symptoms that might be due to an infection.

Seek medical attention **immediately** if you develop symptoms such as:

- -prolonged fever, cough or headache, or
 - localised redness, warmth or swelling of your skin, or
 - persistent cough, weight loss and low-grade fever

Macrophage Activation Syndrome (MAS): Patients with Still's disease may develop a condition called macrophage (a type of white blood cell) activation syndrome (MAS), which can be life-threatening. Tell your doctor right away if your Still's disease symptoms become worse or if you have symptoms of an infection.

- **Pregnancy:** If you received canakinumab while you were pregnant, it is important that you inform the baby's doctor or nurse before any vaccinations are given to your baby. Your baby should not receive live vaccines until at least 16 weeks after you received your last dose of canakinumab before giving birth.

Treatment Indication:

Please make sure to have a LIST OF ALL MEDICATIONS you are taking when visiting a healthcare professional.

Patient's name: _____

For children: parent's/guardian's name: _____

Date of first dose of canakinumab: _____

Canakinumab dose administered: _____

Doctor's name: _____ Doctor's phone: _____

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at <https://www.medicinesauthority.gov.mt/adrportal> and sent by post or email to;

P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann. SGN 3000.
E: postlicensing.medicinesauthority@gov.mt.

Healthcare Professionals may also report any adverse events associated with the use of Ilaris to Novartis Pharma Services Inc., Representative Office, Malta, by phone on +356 21222872, online on www.report.novartis.com or by e-mail at drug_safety.malta@novartis.com.

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For electronic copies of this Educational Material, please refer to the Malta Medicines Authority website - <http://www.medicinesauthority.gov.mt/rmm> - and download the required material with the latest date.

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