IMPORTANT INFORMATION

ILARIS®
(Canakinumab)
PATIENT CARD

150 mg subcutaneous injection

For the treatment of Gouty Arthritis attacks

Novartis Pharma AG
CH-4002 Basel
Switzerland

05/18 GLDEIM/ACZ885/0247

NOVARTIS

Ilaris RMP Vs.11.2/May2018/FA-11537694-1/APR2026

Before starting canakinumab

Infections: You should not be treated with canakinumab if you have an active infection.

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.

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

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: _____

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 Malta 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, Malta 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.novartis.com/report or by e-mail at drug_safety.malta@novartis.com.

Marketing Authorization Holder: Novartis Europharm Limited, Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland.

Local Representative: Novartis Pharma Services Inc., Representative Office Malta.
Tel No.: +356 21222872

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.**

This educational material is a part of the conditions of the Marketing Authorisation.
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For more detailed guidance on Ilaris please refer to the Summary of Product Characteristics (SmPC) available at https://www.ema.europa.eu/en/documents/product-information/ilaris-epar-product-information_en.pdf