IMPORTANT INFORMATION

ILARIS®
(canakinumab)

150 mg subcutaneous injection

For the treatment of Periodic Fever syndromes including:

- Cryopyrin-Associated Periodic Syndromes (CAPS)
- TNF receptor Associated Periodic Syndrome (TRAPS)
- Hyperimmunoglobulin D Syndrome (HIDS) and mevalonate Kinase Deficiency (MKD)
- Familial Mediterranean Fever (FMF)

You can report any problem or adverse events or request additional copies of the materials through:

Patient Safety Department Novartis Pharma AG - Saudi Arabia -.

Toll Free Number: 8001240078
Phone: +966112658100
Fax: +966112658107
Email: adverse.events@novartis.com
Or by online: http://report.novartis.com/

Saudi Food and Drug Authority National Pharmacovigilance Center

Unified Contact Center: 19999
Fax: +966112057662
Email: npc.drug@sfda.gov.sa
Or by online: https://ade.sfda.gov.sa

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA

Ilaris® (canakinumab) SFDA approved RMP
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Before starting canakinumab

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

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 Guide

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: ----------