IMPORTANT INFORMATION

ILARIS®

(canakinumab)

150 mg subcutaneous injection

Cryopyrin-Associated Periodic Syndromes (CAPS)

You can report any side effects or adverse events through:

Novartis Consulting AG.

Saudi Arabia: P.O. Box 16032, Riyadh 11464, Tel: +966114658882

DS&E

Phone: +996112658100

Fax: +966112658107

Email: adverse.events@novartis.com

National pharmacovigilance and drug safety center

Toll free phone: 8002490000

Fax: +966112057662

E-mail: npc.drug@sfda.gov.sa

Or by online: https://ade.sfda.gov.sa

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NOVARTIS PHARMACEUTICALS

Before starting canakinumab

Infections: You should not be treated with canakinumab if you have before starting treatment with canakinumab.

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

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 : ----------

Doctor's name: ----------

Doctor's phone: ----------