For the treatment of Periodic Fever syndromes including: Cryopyrin-Associated Periodic Syndrome (TRAPS) TNF receptor Associated Periodic Syndrome (HNDS)/ Hyperimmunoglobulin D Syndrome (HNDS)/ Mevalonate Kinase Deficiency (MKD) Familial Mediterranean Fever (FMF)

150 mg subcutaneous injection

If you get any side effects, talk to your doctor, pharmacist or nurse.

By reporting side effects, you can help provide more information on the safety of this medicine.

You can report side effects directly via HPRA Pharmacovigilance, website: www.hpra.ie.

Side effects could also be reported to Novartis preferably via www.report.novartis.com, or by email to drugsafety.dublin@novartis.com or by calling 01 2080 612.

Additional information on canakinumab is available in the Patient Information Leaflet.

A copy of this leaflet will be provided within the canakinumab packaging

Novartis Ireland Ltd, The Vista Building, Elm Park Business Park, Merrion Road, Dublin 4 IE156523 (RMP Version 12)

Date of Preparation: September 2021 Approved by the HPRA: 22nd October 2021



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 Indication

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

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For children: parent's/guardian's name:
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Date of most recent dose of canakinumab:
Canakinumah dosa administered:

Doctor's name:

Detiont's name

Doctor's phone: