PATIENT FACT SHEET

Canakinumab (Ilaris)

WHAT IS IT?

Canakinumab [Ilaris] is an interleukin-1 [IL-1] blocker, which works to suppress the production of an inflammatory protein in the body. IL-1 is a pro-inflammatory protein released in states of infection and inflammation. Overproduction of IL-1 creates a systemic inflammation leading to symptoms such as fever, joint pain, and rashes. Canakinumab is a monoclonal antibody which binds to the IL-1 protein, thus preventing it from attaching to its cellular receptor. As a result, canakinumab stops the inflammatory response commonly seen in autoinflammatory disorders.

Canakinumab is approved by the FDA for the treatment of Cryopyrin-associated periodic syndromes (CAPS, including Familial Cold Autoinflammatory Syndrome, Muckle-Wells, and Neonatal Onset Multisystem Inflammatory Disease [NOMID]), Tumor Necrosis Factor Receptor Associated Periodic Syndrome [TRAPS], Hyperimmunoglobulin D Syndrome [HIDS]/ Mevalonate Kinase Deficiency [MKD], Familial Mediterranean Fever [FMF] and Systemic Juvenile Idiopathic Arthritis [SJIA].

HOW TO TAKE IT

Canakinumab is a subcutaneous injection. Dosing schedules differ based on the disease, listed as follows:

- **Cryopyrin Associated Periodic Syndrome**
  - 150 mg for CAPS patients with body weight greater than 40 kg, or 2 mg/kg for CAPS patients with body weight greater than or equal to 15 kg and less than or equal to 40 kg.
  - For those with an inadequate response, the dose or frequency can be increased.
  - It is administered subcutaneously every 8 weeks.

- **Tumor Necrosis Factor Receptor Associated Periodic Syndrome**
- **Hyperimmunoglobulin D Syndrome [HIDS] / Mevalonate kinase deficiency [MKD]**
- **Familial Mediterranean Fever [FMF]**
  - Body weight less than or equal to 40 kg: The starting dose is 2 mg/kg administered subcutaneously every 4 weeks. The dose can be increased to 4 mg/kg every 4 weeks if the clinical response is not adequate.
  - Body weight greater than 40 kg: The starting dose is 150 mg every 4 weeks. The dose can be increased to 300 mg every 4 weeks if the clinical response is not adequate.

- **Systemic juvenile idiopathic arthritis [SJIA]**
  - The dose is 4 mg/kg every 4 weeks, up to a maximum dose of 300 mg per dose.

SIDE EFFECTS

A documented allergy to canakinumab is an absolute contraindication to the drug. Side effects include nasopharyngitis, influenza, rhinitis, nausea, headache, upper respiratory infection, gastroenteritis and vertigo. Injection site reactions are the most common adverse event and have been reported in greater than 10% of patient treated with Canakinumab.

TELL YOUR DOCTOR

Since canakinumab suppresses your natural immune response, it can cause infections. Tell your doctor if you develop fevers or any signs or symptoms of an infection. If you experience any allergies to canakinumab, you should stop treatment and contact your doctor. Tell your doctor if you are pregnant or planning on conceiving soon. You should discuss with your doctor before receiving any live vaccinations. Live vaccines should be avoided while on this medication and you should discuss updating your vaccinations prior to starting this medication.

REFERENCES

https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/BLA125319_858687lbl.pdf