RXADVANCE
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Ilaris (canakinumab) Injection
Clinical Update

Clinical update: FDA Approval for New Indication to Treat Adult-Onset Still's Disease (AOSD).
FDA approval date: June 16, 2020

Ilaris (canakinumab) is a human anti-interleukin-1β monoclonal antibody for the treatment of Periodic Fever Syndromes (Cryopyrin-Associated Periodic Syndromes, Tumor Necrosis Factor Receptor Associated Periodic Syndrome, Hyperimmunoglobulin D Syndrome/Mevalonate Kinase Deficiency, Familial Mediterranean Fever), and active Still's disease, including Adult-Onset Still's Disease (AOSD) and Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged 2 years and older.

The efficacy of Ilaris in adults with AOSD is based on the pharmacokinetic exposure and extrapolation of the established efficacy of Ilaris in SJIA patients. Efficacy of Ilaris was also assessed in a randomized, double-blind, placebo-controlled study that enrolled 36 patients (22 to 70 years old) diagnosed with AOSD. The efficacy and safety data in AOSD were generally consistent with the results of a pooled analysis of SJIA patients.
Ilaris is contraindicated in patients with confirmed hypersensitivity to the active substance.
The most common adverse drug reactions greater than 10% associated with Ilaris treatment in SJIA patients were infections (nasopharyngitis and upper respiratory tract infections), abdominal pain, and injection site reactions.