



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 March 2020
EMA/CHMP/114338/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Kineret anakinra

On 26 March 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Kineret. The marketing authorisation holder for this medicinal product is Swedish Orphan Biovitrum AB (publ).

The CHMP adopted a new indication as follows:

Kineret is indicated for the treatment of Familial Mediterranean Fever (FMF). Kineret should be given in combination with colchicine, if appropriate.

For information, the full indications for Kineret will be as follows:

Rheumatoid Arthritis (RA)

Kineret is indicated in adults for the treatment of the signs and symptoms of RA in combination with methotrexate, with an inadequate response to methotrexate alone.

Periodic fever syndromes

Kineret is indicated for the treatment of the following autoinflammatory periodic fever syndromes in adults, adolescents, children and infants aged 8 months and older with a body weight of 10 kg or above:

Cryopyrin-Associated Periodic Syndromes (CAPS)

Kineret is indicated for the treatment of CAPS, including:

- Neonatal-Onset Multisystem Inflammatory Disease (NOMID) / Chronic Infantile Neurological, Cutaneous, Articular Syndrome (CINCA)
- Muckle-Wells Syndrome (MWS)
- Familial Cold Autoinflammatory Syndrome (FCAS)

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion



Familial Mediterranean Fever (FMF)

Kineret is indicated for the treatment of Familial Mediterranean Fever (FMF). Kineret should be given in combination with colchicine, if appropriate.

Still's Disease

Kineret is indicated in adults, adolescents, children and infants aged 8 months and older with a body weight of 10 kg or above for the treatment of Still's disease, including Systemic Juvenile Idiopathic Arthritis (SJIA) and Adult-Onset Still's Disease (AOSD), with active systemic features of moderate to high disease activity, or in patients with continued disease activity after treatment with non-steroidal anti-inflammatory drugs (NSAIDs) or glucocorticoids.

Kineret can be given as monotherapy or in combination with other anti-inflammatory drugs and disease-modifying antirheumatic drugs (DMARDs).

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.