EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2013
EMA/CHMP/569575/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Kineret

anakinra

On 19 September 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion for an extension application for the Marketing Authorisation for the medicinal product Kineret to add a new strength 100mg/0.67 ml solution for injection in a pre-filled syringe for a new indication in adult and paediatric patients for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS). The prefilled syringe also allows the administration of the approved dosage required in patients with Rheumatoid Arthritis. The marketing authorisation holder for this medicinal product is Swedish Orphan Biovitrum AB (publ). They may request a re-examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The approved indications for this new strength are as follows:

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

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 Cryopyrin-Associated Periodic Syndromes (CAPS), including:

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

Detailed conditions 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 the variation to the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.

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