22 February 2018
EMA/84249/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Kineret

anakinra

On 22 February 2018, 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 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)."

For information, the full indications for Kineret will be as follows[2]:

> "Kineret is indicated in adults for the treatment of the signs and symptoms of Rheumatoid Arthritis (RA) in combination with methotrexate, 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)

[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
[2] New text in bold

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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)."

In addition the CHMP adopted the removal of the following contraindication:

"Kineret must not be used in patients with severe renal impairment (CLcr < 30 ml/minute) (see section 4.2)."

For information, the full contraindications for Kineret will be as follows[3]:

"Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 or to E. coli derived proteins.

~~Kineret must not be used in patients with severe renal impairment (CLcr < 30 ml/minute) (see section 4.2).~~

Kineret treatment must not be initiated in patients with neutropenia (ANC <1.5 x 109/l) (see section 4.4)."

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.

[3] Removed text as strikethrough