KINERET® (anakinra) - Prescribing Information for United Kingdom

Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Composition: Each pre-filled syringe contains 100 mg of anakinra per 0.67ml (150 mg/ml).

Indications: 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 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) (including: Neonatal-Onset Multisystem Inflammatory Disease (NOMID) / Chronic Infantile Neurological, Cutaneous, Articular Syndrome (CINCA), Muckle-Wells Syndrome (MWS) and Familial Cold Autoinflammatory Syndrome (FCAS) and Familial Mediterranean Fever (FMF) (KINERET should be given in combination with colchicine, if appropriate). 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).

Dosage and administration: KINERET treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of RA, CAPS, FMF and Still's disease, respectively. RA: Adults. The recommended dose is 100 mg administered once a day at approximately the same time each day by subcutaneous injection. CAPS: Adults, adolescents, children, and infants aged 8 months and older with a body weight of 10 kg or above: The recommended starting dose is 1-2 mg/kg/day by subcutaneous injection. The therapeutic response is primarily reflected by reduction in clinical symptoms such as fever, rash, joint pain, and headache, but also in inflammatory serum markers (CRP/SAA levels), or occurrence of flares. Maintenance dose in mild CAPS (FCAS, mild MWS): Patients are usually well-controlled by maintaining the recommended starting dose (1-2 mg/kg/day). Maintenance dose in severe CAPS (MWS and NOMID/CINCA): Dose increases may become necessary within 1-2 months based on therapeutic response. The usual maintenance dose in severe CAPS is 3-4 mg/kg/day, which can be adjusted to a maximum of 8 mg/kg/day. In addition to the evaluation of clinical symptoms and inflammatory markers in severe CAPS, assessments of inflammation of the CNS, including the inner ear (MRI or CT, lumbar puncture, and audiology) and eyes (ophthalmological assessments) are recommended after an initial 3 months of treatment, and thereafter every 6 months, until effective treatment doses have been identified. When patients are clinically well-controlled, CNS and ophthalmological monitoring may be conducted yearly. FMF or Still's Disease: The recommended dose for patients weighing 50 kg or more is 100 mg/day by subcutaneous injection. Patients weighing less than 50 kg should be dosed by body weight with a recommended dose of 1-2 mg/kg/day. In Still's disease, response to treatment should be evaluated after 1 month: In case of persistent systemic manifestations dose may be adjusted in children or continued treatment with KINERET should be reconsidered by the treating physician. Please consult SmPC section 6.6 for full instructions for use and handling information. Paediatric population (< 18 years): No data are available in children under the age of 8 months. In children with inadequate response, the dose can be escalated up to 4 mg/kg/day. The efficacy data of KINERET in children under 2 years of age with FMF are limited. Elderly population (≥ 65 years): There is limited experience in patients ≥ 65 years, but no dose adjustments are expected to be required. Hepatic impairment: No dose adjustment is required for patients with moderate hepatic impairment (Child-Pugh Class B). KINERET should be used with caution in patients with severe hepatic impairment. Renal impairment: No dose adjustment is needed for patients with mild renal impairment (CLcr 60 to 89ml/min). KINERET should be used with caution in patients with moderate renal impairment (CLcr 30 to 59ml/min). In patients with severe renal impairment (CLcr <30ml/min) or end stage renal disease, including dialysis, administration of the prescribed dose of KINERET every other day should be considered. KINERET is administered by subcutaneous injection. Alternating the injection site is recommended to avoid discomfort at the site of injection. Cooling of the injection site, warming the injection liquid to room temperature, use of cold packs (before and after the injection), and use of topical glucocorticoids and antihistamines after the injection can alleviate the signs and symptoms of injection site reactions.

Contraindications: Hypersensitivity to the active substance or to any of the excipients or to E. coli derived proteins. KINERET must not be initiated in patients with neutropenia (ANC <1.5 × 10^9/l).

Special warnings and precautions for use: Allergic reactions: including anaphylactic reactions and angioedema have been reported uncommonly (majority were maculopapular or urticarial rashes). If a severe allergic reaction occurs, administration of KINERET should be discontinued and appropriate treatment initiated. Hepatic events: Hepatic events in patients with Still's disease predominantly occur during the first month of treatment. Routine testing of hepatic enzymes during the first month should be considered. The efficacy and safety of KINERET patients with AST/ALT ≥ 1.5 x upper level of normal have not been evaluated. KINERET should be used with caution in patients with severe hepatic impairment. Serious infections: Physicians should exercise caution when administering KINERET to patients with a history of recurring infections or with underlying conditions which may predispose them to infections. KINERET treatment should not be initiated in patients with active infections. KINERET treatment should be discontinued in RA patients if a serious infection develops. In KINERET treated CAPS or FMF patients, there is a risk for disease flares when discontinuing KINERET treatment. With careful monitoring, KINERET treatment can be continued also during a serious infection. Patients should be screened for latent tuberculosis and viral hepatitis prior to initiating KINERET. Renal impairment: KINERET should be used with caution in patients with moderate renal impairment (CLcr 30 to 59ml/min). In patients with severe renal impairment (CLcr <30 ml/min) or end-stage renal disease, including dialysis, administration of the prescribed dose of KINERET every other day should be considered. Neutropenia: KINERET treatment should not be initiated in patients with neutropenia (Absolute Neutrophil Count (ANC) < 1.5 × 10^9/l). It is recommended that neutrophil counts be assessed prior to initiating KINERET treatment, and while receiving KINERET, monthly during the first 6 months of treatment and quarterly hereafter. In patients who become neutropenic (ANC < 1.5 × 10^9/l) the ANC should be monitored closely and KINERET treatment should be discontinued. Pulmonary Events: A causal relationship between Kineret and pulmonary events has not been established. Drug reaction with eosinophilia and systemic symptoms (DRESS): During post-marketing use, DRESS has rarely been reported in patients treated with KINERET, predominantly in paediatric patients with Still's disease [systemic juvenile idiopathic arthritis (SJIA)]. Patients with DRESS may require hospitalisation, as this condition may be fatal. If signs and symptoms of DRESS are present and an alternative aetiology cannot be established, KINERET should be discontinued, and a different treatment considered. Amyloidosis (Systemic): In patients with NOMID/CINCA who received high doses of KINERET over extended periods of time and presented with injection site amyloid deposits (see section 4.8) isolated cases of systemic AIL1RAP (IL-1 receptor antagonist protein) amyloidosis have been reported during post-marketing use. In patients with confirmed injection site amyloid deposits, observation for symptoms of systemic amyloidosis, including close monitoring for proteinuria, is recommended. Immunosuppression: The impact of treatment with KINERET on pre-existing malignancy has not been studied. Therefore, the use of KINERET in patients with pre-existing malignancy is not recommended. Vaccinations: No data are available on either the effects of live vaccination or on the secondary transmission of infection by live vaccines in patients receiving KINERET. Therefore, live vaccines should not be given concurrently with KINERET. Elderly population (≥ 65 years): Because there is a higher incidence of infections in the elderly population in general, caution should be used in treating elderly patients. Concurrent KINERET and TNF-α antagonist treatment: The concurrent administration of KINERET and etanercept or other TNF-α antagonists is not recommended. Traceability: In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. Excipients: This medicinal product contains less than 1 mmol sodium (23 mg) per 100 mg dose, which is to say essentially 'sodium-free'. This medicinal product contains 0.70 mg of polysorbate 80 in each pre-filled syringe, which is equivalent to 1.04 mg/ml. Polysorbates may cause allergic reactions.

Interactions: Concurrent KINERET and TNF-α antagonist treatment: The concurrent use of KINERET with etanercept or any other TNF-α antagonist is not recommended. Cytochrome P450 Substrates: Upon start or end of KINERET treatment in patients on these types of medicinal products, it may be relevant to consider therapeutic monitoring of the effect or concentration of these products, and the individual dose of the medicinal product may need to be adjusted.

Fertility, pregnancy, and lactation: There are limited amount of data from the use of KINERET in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of KINERET during pregnancy and in women of childbearing potential not using contraception. Breast-feeding should be discontinued during treatment with KINERET.

Undesirable effects: Please consult SmPC section 4.8 for the full list of possible adverse reactions. The adverse reactions at least possibly related to treatment are listed below as very common (≥1/10) and common (≥1/100 to <1/10). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness. Very common adverse reactions: Headache, Blood Cholesterol Increased and Injection Site Reactions (ISRs). Common adverse reactions: Serious Infections, Neutropenia, Thrombocytopenia. For uncommon adverse reactions consult the SmPC section 4.8. ISRs typically appear within 2 weeks of therapy and disappear within 4-6 weeks. The development of ISRs in patients who had not previously experienced ISRs was uncommon after the first month of therapy. Injection site amyloid deposits: During post-marketing use, isolated cases of injection site amyloid deposits have been reported in patients with NOMID/CINCA who received high doses of KINERET injected subcutaneously into the same area of skin over long periods of time. Rotation of injection sites is therefore recommended.

Legal Category: Prescription Only Medicine (POM). **Marketing Authorisation No.**: PLGB 30941/0018. **Pack size:** 7 pre-filled syringes. **Price**: NHS List Price £183.61 per pack. **Marketing Authorisation Holder:** Swedish Orphan Biovitrum AB (publ), SE-112 76 Stockholm, Sweden. **Further information available from:** Swedish Orphan Biovitrum (UK) Ltd, Suite 2, Riverside 3, Granta Park, Great Abington, Cambridgeshire, CB21 6AD. **Date of Preparation:** December 2025 **Company Reference:** PP-31010

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Swedish Orphan Biovitrum Ltd by email at medical.info.uk@sobi.com or by calling +44 (0) 800 111 4754.