19 May 2022
EMA/253572/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Kinpeygo

budesonide

On 19 May 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional[2] marketing authorisation for the medicinal product Kinpeygo[3], intended for the treatment of primary immunoglobulin A nephropathy. The applicant for this medicinal product is Calliditas Therapeutics AB.

Kinpeygo will be available as a 4 mg modified-release hard capsule. The active substance of Kinpeygo is budesonide, a corticosteroid (ATC code: A07EA06) which mainly acts locally in the intestines to reduce the inflammation associated with primary immunoglobulin A nephropathy.

The benefit of Kinpeygo is its ability to effectively reduce proteinuria. The most common side effects are increased blood pressure, swelling of arms or legs (such as ankle swelling), cushingoid features (such as rounded face, increased body hair, weight gain and acne), and indigestion.

Kinpeygo is a hybrid medicine[4] of Entocort which has been authorised in the EU since 2 April 1992. Kinpeygo contains the same active substance as Entocort but has a different formulation and a different indication.

The full indication is:

> Kinpeygo is indicated for the treatment of primary immunoglobulin A (IgA) nephropathy (IgAN) in adults at risk of rapid disease progression with a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/gram.

Detailed recommendations for the use of this product will be described in the summary of product

[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] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is expected to provide comprehensive clinical data at a later stage.
[3] This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained
[4] Hybrid applications rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data.

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characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.