30 May 2024
EMA/233577/2024
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (post authorisation)**

# Kinpeygo

budesonide

On 30 May 2024, 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 Kinpeygo. The marketing authorisation holder for this medicinal product is STADA Arzneimittel AG.

The CHMP adopted an extension to the existing indication as follows:[2]

> Kinpeygo is indicated for the treatment of **adults with** primary immunoglobulin A ~~(IgA)~~ nephropathy (IgAN) ~~in adults at risk of rapid disease progression~~ with a urine protein **excretion**~~-to-creatinine ratio (UPCR)~~ ≥1.**0**~~5~~ g/**day**~~gram~~ **(or urine protein-to-creatinine ratio ≥0.8 g/g).**

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 made available in all official European Union languages after a decision on this change 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 67 days from adoption of the opinion
[2] New text in bold, removed text as strikethrough

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