10 December 2020
EMA/CHMP/650319/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Sibnayal

potassium citrate / potassium hydrogen carbonate

On 10 December 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Sibnayal[2], intended for the treatment of distal renal tubular acidosis. The applicant for this medicinal product is Advicenne S.A.

Sibnayal will be available as 8 and 24 mEq prolonged-release granules. The active substances of Sibnayal are potassium citrate and potassium hydrogen carbonate, mineral supplements (ATC code: A12BA30) acting as alkalising agents and a buffer in metabolic acidosis.

The benefit with Sibnayal is its ability to correct metabolic acidosis in patients with distal renal tubular acidosis. This condition can lead to renal function impairment, weaken muscle strength and affect bone structure, and it can result in adults of short stature if left untreated.

The most common side effects are abdominal pain, gastro-intestinal pain and nausea.

The full indication is:

> Sibnayal is indicated for the treatment of distal renal tubular acidosis (dRTA) in adults, adolescents and children aged one year and older.

It is proposed that Sibnayal be subject to medical prescription.

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

[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] This product was designated as orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

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