



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 March 2026
EMA/CHMP/73735/2026
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Bopediat furosemide

On 26 March 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a paediatric use marketing authorisation (PUMA) for the medicinal product Bopediat, intended for the treatment of children with oedema of cardiac or renal origin, oedema of hepatic origin and hypertension in children with chronic kidney disease.

The applicant for this medicinal product is Proveca Pharma Limited.

Bopediat will be available as 5 mg orodispersible tablets. The active substance of Bopediat is furosemide, a loop diuretic (ATC code: C03CA01). At usual therapeutic doses, the main effect of furosemide is on the ascending limb of the loop of Henle, where it inhibits the reabsorption of sodium chloride. It has a secondary effect on the proximal tubule and dilution segment. In addition, furosemide increases renal blood flow to the renal cortex.

Bopediat is a hybrid medicine² of Lasilix Faible 20 mg tablets (furosemide) which has been authorised in France since April 1977. Bopediat contains the same active substance as Lasilix Faible 20 mg tablets, but it is available as orodispersible tablets and at a lower strength so that it can be given to young children.

Studies have demonstrated the satisfactory quality of Bopediat and its bioequivalence to the reference product Lasilix Faible 20 mg tablets.

The full indication is:

Bopediat is indicated in children from birth to less than 18 years of age for the treatment of oedema of cardiac or renal origin, oedema of hepatic origin, and hypertension in patients with chronic kidney disease.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website 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 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.

