EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 February 2017
EMA/CHMP/99882/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Natpar

parathyroid hormone

On 23 February 2017, 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 Natpar, intended for the treatment of hypoparathyroidism. Natpar was designated as an orphan medicinal product on 18 December 2013. The applicant for this medicinal product is Shire Pharmaceuticals Ireland Ltd.

Natpar will be available as powder (25, 50, 75 and 100 micrograms) and solvent for solution for injection. The active substance of Natpar is parathyroid hormone (ATC code: H05AA03). Natpar is intended as a replacement therapy for endogenous parathyroid hormone, a principal regulator of calcium and phosphate homeostasis.

The main benefits with Natpar are its ability to reduce the patient's need for calcium and vitamin D supplements while maintaining serum calcium levels within the desired range and partially improving some parameters of calcium-phosphate metabolism. The most common side effects are hypercalcaemia and hypocalcaemia.

The full indication is: "Natpar is indicated as adjunctive treatment of adult patients with chronic hypoparathyroidism who cannot be adequately controlled with standard therapy alone". It is proposed that Natpar be prescribed by physicians experienced in the treatment of hypoparathyroidism.

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] 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 likely to provide comprehensive clinical data at a later stage.

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