



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 November 2018
EMA/126024/2019
Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): parathyroid hormone

Procedure No. EMEA/H/C/PSUSA/00010591/201804

Period covered by the PSUR: 24 October 2017 to 23 April 2018



Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for parathyroid hormone, the scientific conclusions of CHMP are as follows:

A signal of nephrolithiasis was evaluated during the reporting interval. On review of the data provided, the PRAC considers that an association between Natpar and nephrolithiasis cannot be excluded and recommends that a warning should be included in the product information. The Package Leaflet is updated in accordance.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for parathyroid hormone the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing parathyroid hormone is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.