29/04/2022

Natpar (parathyroid hormone) 100 micrograms/dose powder and solvent for solution for injection: expected shortage from June 30th, 2022

Marketing Authorisation Number EU/1/15/1078/004

Dear Healthcare Professional,

Takeda, in agreement with the European Medicines Agency and the <National Competent Authority> would like to inform you of the following:

Summary

- **Due to manufacturing challenges, Takeda will be unable to supply the 100 micrograms/dose strength from approximately end of June 2022. The duration is unknown but is expected to last at least 6 months.**
- **Healthcare professionals are advised not to initiate any new patients on any strength of Natpar until the supply issue is resolved.**
- **For existing patients on 100 mcg once a day, once the 100 micrograms / dose strength is unavailable, healthcare professionals can prescribe an alternative dosing regimen, as per their independent clinical judgment (see details below).**
- **It is very important to closely monitor serum calcium levels and observe patients for signs and symptoms of hypocalcemia while carefully adjusting active vitamin D and supplemental calcium doses in all patients affected by Natpar 100 micrograms/dose shortage.**

Background on the concern

Natpar is indicated as adjunctive treatment of adult patients with chronic hypoparathyroidism who cannot be adequately controlled with standard therapy alone. Due to manufacturing challenges, Takeda will be unable to supply the 100 micrograms/dose strength from approximately end of June 2022. The duration is unknown but is expected to last at least 6 months.

Alternative dosing options

For patients already on Natpar 100 micrograms/dose, Takeda would like to make you aware of the following alternative dosing options:

- Multiple dosing: If HCPs believe, in their independent clinical judgement, a 100 micrograms dose is necessary for their patients, they can prescribe two separate injections of Natpar 50 micrograms/dose. If the HCP decides to prescribe 2 consecutive doses of Natpar 50 micrograms/dose, the second dose should be administered in the contralateral thigh using a new needle within 15 minutes of the first dose. HCPs should consider monitoring of serum calcium levels and adjustment, as necessary, of exogenous calcium and/or active vitamin D.

  Or

- Reduced dosing: Natpar 75 micrograms/dose remains available for whom, in the HCP's independent clinical judgement, a reduced dose of Natpar 75 micrograms is appropriate. HCPs should consider monitoring of serum calcium levels and adjustment, as necessary, of exogenous calcium and/or active vitamin D.

It is imperative that the attached patient information, *'Patient/Caregiver Injection Instructions for Natpar 100 micrograms/dose shortage'* is given to the patient and that the patient is sufficiently educated. HCPs should go through the patient education materials with the patient, to make sure they are understood.

For patients receiving 2 x Natpar 50 micrograms/dose, make sure to communicate the following:

One dose of Natpar 50 micrograms/dose should be injected in each thigh. A new needle should be used for each injection and the dose indicator checked to confirm two doses of 50mcg have been administered. To reduce the chance of local reactions, the injections should alternate between upper and lower parts of the thighs each day. The two doses should be taken less than 15 minutes apart; however if the patient by error takes only one dose, they should take the second dose as soon as possible and contact their doctor. The patient must be educated on the importance of correct dosing, and to contact the HCP in case of any error in dosing.

For patients where the dose is reduced from Natpar 100 micrograms/day to Natpar 75 micrograms/day, make sure to communicate the following:

The reduction in dose places the patient at increased risk of hypocalcemia. This must be communicated to the patient, informing them of the signs of hypocalcaemia and on when they should inform their doctor.

For all patients affected by the drug shortage:

It is very important to closely monitor serum calcium levels and observe for signs and symptoms of hypocalcemia while carefully adjusting active vitamin D and supplemental calcium doses in any patient affected by the Natpar 100 micrograms/dose shortage. Please review the SmPC Section 4.2 (Interruption or discontinuation of treatment) and Section 4.4 (Warnings and Precautions: Hypocalcemia).

No new patients on Natpar:

In order to ensure that existing patients can continue to receive treatment, HCPs are asked not to initiate any new patients **on any strength of Natpar**.

There is a possibility that the 75 micrograms / dose strength may be similarly affected by a shortage later in 2022, so this should also be considered as part of the decision to choose an alternate dosing option as detailed above. Should a shortage occur for the 75 micrograms / dose, further communications will be issued to HCPs, to allow them to manage patients appropriately.

Call for reporting

Please report any adverse events experienced by your patients taking Natpar. When reporting, please provide as much information as possible including information about batch details, medical history, any concomitant medication, onset and treatment dates.

Please report suspected adverse reactions with any medicine or vaccine to the <Competent Health Authority (e.g. Website, email, Address, Contact no.)>

Adverse events should also be reported to Takeda: <insert local contact details>

Company Contact Point

For questions relating to the content of this communication please contact the Takeda Medical Information Department:

medinfoEMEA@takeda.com

<Insert LOC contact phone and email>

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Yours faithfully,
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