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EPAR summary for the public

Natpar

parathyroid hormone

This is a summary of the European public assessment report (EPAR) for Natpar. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Natpar.

For practical information about using Natpar, patients should read the package leaflet or contact their doctor or pharmacist.

What is Natpar and what is it used for?

Natpar is a hormone replacement medicine for treating adults with under-active parathyroid glands, a condition known as hypoparathyroidism.

In patients with this condition, the parathyroid glands in the neck do not produce enough parathyroid hormone which controls the level of calcium in the blood. As a result, patients have low levels of calcium which can cause problems in bones, muscles, heart, kidneys and other parts of the body.

Natpar is used as an add-on to treatment with calcium and vitamin D supplements when these treatments have not worked well enough.

Because the number of patients with hypoparathyroidism is low, the disease is considered ‘rare’, and Natpar was designated an ‘orphan medicine’ (a medicine used in rare diseases) on 18 December 2013.

Natpar contains the active substance parathyroid hormone.

How is Natpar used?

Natpar is available as a powder and a liquid that are mixed together to make a solution for injection. Natpar is injected under the skin of the thigh using the Natpar pen. The usual recommended starting dose is 50 micrograms once a day. The dose of Natpar, as well as the patient’s dose of the vitamin D

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and calcium supplements, is then adjusted on the basis of the patient's blood calcium levels. The maximum daily dose is 100 micrograms.

Patients can inject Natpar themselves once they have been trained. The medicine can only be obtained with a prescription and treatment should be supervised by a healthcare professional experienced in the management of patients with hypoparathyroidism. For further information, see the package leaflet.

How does Natpar work?

The active substance in Natpar, parathyroid hormone, is a copy of the natural hormone produced by the parathyroid glands. It replaces the missing hormone in patients with hypoparathyroidism, thus helping to restore calcium levels.

What benefits of Natpar have been shown in studies?

Natpar has been shown to help control blood calcium levels in patients with hypoparathyroidism who are receiving calcium and vitamin D supplements.

In a main 24-week study involving 124 patients, 54.8% (46 out of 84) of the patients who received Natpar achieved and maintained acceptable blood calcium levels while reducing their doses of calcium and vitamin D supplements by at least 50%. The proportion of patients taking placebo (a dummy treatment) who achieved the same was 2.5% (1 out of 40 patients).

What are the risks associated with Natpar?

The most common side effects with Natpar (which may affect more than 1 in 10 people) are too high or too low blood calcium levels, which can lead to headache, diarrhoea, vomiting, paraesthesia (unusual sensations like pins and needles), hypoaesthesia (reduced sense of touch) and high calcium levels in the urine. For the full list of all side effects reported with Natpar, see the package leaflet.

Natpar must not be used in patients who are having or have had radiation therapy to the bones, who have bone cancer or cancer that has spread to the bones and are at increased risk of developing a bone cancer called osteosarcoma. Natpar must also not be used in patients who have unexplained increases in the levels of an enzyme called bone alkaline phosphatase and those who have pseudohypoparathyroidism, a rare disease where the body does not respond adequately to the parathyroid hormone produced by the body. For the full list of restrictions, see the package leaflet.

Why is Natpar approved?

Natpar replaces the missing parathyroid hormone in patients with hypoparathyroidism. While the main study showed that Natpar helps control blood calcium levels while reducing the need for calcium and vitamin D supplements, the study was of short duration and there was no evidence of improvements in patients' quality of life or reductions in long-term problems such as kidney impairment. Therefore, Natpar should only be used in patients who are not adequately controlled with standard treatments alone, who do not have other treatment options.

Regarding safety, the risk of calcium levels becoming too high or too low is considered important and further data are needed to better understand the consequences of wide fluctuations in blood calcium level after the medicine is given once a day.

Because of the limited data available, Natpar has been given 'conditional approval'. This means that there is more evidence to come about the medicine, which the company is required to provide. Every

year, the European Medicines Agency will review any new information that becomes available and this summary will be updated as necessary.

What information is still awaited for Natpar?

Since Natpar has been granted a conditional approval, the company that markets Natpar will conduct a further study to confirm the benefits and risks of the medicine and the appropriateness of the once-a-day dosing schedule.

What measures are being taken to ensure the safe and effective use of Natpar?

The company that markets Natpar will set-up a registry and collect long-term data on patients treated with Natpar, including its effects on bones, kidneys and patients' quality of life.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Natpar have also been included in the summary of product characteristics and the package leaflet.

Other information about Natpar

The European Commission granted a marketing authorisation valid throughout the European Union for Natpar on 24 April 2017.

The full EPAR for Natpar can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Natpar, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for Natpar can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Rare disease designation.

This summary was last updated in 04-2017.