EMA/432465/2023
EMEA/H/C/005934

Yorvipath (*palopegteriparatide*)

An overview of Yorvipath and why it is authorised in the EU

What is Yorvipath and what is it used for?

Yorvipath is a hormone replacement medicine for treating adults with chronic hypoparathyroidism.

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

Hypoparathyroidism is rare, and Yorvipath was designated an 'orphan medicine' (a medicine used in rare diseases) on 19 October 2020. Further information on the orphan designation can be found on the EMA website.

Yorvipath contains the active substance palopegteriparatide.

How is Yorvipath used?

Yorvipath is given as an injection under the skin using a pre-filled pen. The medicine can only be obtained with a prescription. Treatment should be started and monitored by a doctor or a qualified healthcare professional experienced in the diagnosis and management of patients with chronic hypoparathyroidism.

For more information about using Yorvipath, see the package leaflet or contact your doctor or pharmacist.

How does Yorvipath work?

The active substance in Yorvipath, palopegteriparatide, is changed in the body into teriparatide, a shortened form of PTH. Teriparatide replaces the missing hormone in patients with hypoparathyroidism, acting through bone tissue and the kidneys to help restore calcium levels.

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What benefits of Yorvipath have been shown in studies?

One main study involving 84 patients with hypoparathyroidism showed that Yorvipath was effective at keeping blood calcium levels within the normal range, compared with placebo. Around 79% (48 out of 61) of patients given Yorvipath for 26 weeks achieved normal blood calcium levels, no longer needed standard treatments (active vitamin D and high-dose calcium supplements) and were on a stable dose of the medicine. This compared with 5% (1 out of 21) of patients given placebo.

What are the risks associated with Yorvipath?

For the full list of side effects and restrictions with Yorvipath, see the package leaflet.

The most common side effects with Yorvipath (which may affect more than 1 in 10 people) include injection site reactions, headache and paraesthesia (unusual sensations like pins and needles).

Yorvipath must not be used in patients who have pseudohypoparathyroidism, a condition in which the body does not adequately respond to the parathyroid hormone produced by the body.

Why is Yorvipath authorised in the EU?

Yorvipath replaces the missing parathyroid hormone in patients with chronic hypoparathyroidism, and the results of the main study showed that most patients given the medicine had blood calcium levels within the normal range and no longer needed therapeutic doses of calcium supplements and active vitamin D to control their disease. In addition, side effects are considered to be manageable.

The European Medicines Agency therefore decided that Yorvipath's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

As for all medicines, data on the use of Yorvipath are continuously monitored. Side effects reported with Yorvipath are carefully evaluated and any necessary action taken to protect patients.

Other information about Yorvipath

Yorvipath received a marketing authorisation valid throughout the EU on 17 November 2023.

Further information on Yorvipath can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/yorvipath.

This overview was last updated in 11-2023.