EMA/753097/2016
EMEA/H/C/004368

EPAR summary for the public

Movymia

teriparatide

This is a summary of the European public assessment report (EPAR) for Movymia. 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 Movymia.

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

What is Movymia and what is it used for?

Movymia is a medicine used for the treatment of osteoporosis (a disease that makes bones fragile) in:

- women who have been through the menopause. In these patients, Movymia has been shown to significantly reduce vertebral (spine) and non-vertebral fractures (broken bones), but not those of the hip;
- men who are at an increased risk of fractures;
- men and women who are at an increased risk of fractures due to long-term treatment with glucocorticoids (a type of steroid).

Movymia contains the active substance teriparatide.

Movymia is a 'biosimilar medicine'. This means that Movymia is highly similar to a biological medicine (also known as the 'reference medicine') that is already authorised in the European Union (EU). The reference medicine for Movymia is Forsteo. For more information on biosimilar medicines, see the question-and-answer document here.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

How is Movymia used?

Movymia is available as a solution for injection in cartridges (containing 600 micrograms of teriparatide) intended to be used with ServoPen Fix system. The recommended dose is 20 micrograms of Movymia given once a day as an injection under the skin of the thigh or abdomen (belly). Patients may inject themselves once they have been trained.

Patients should receive calcium and vitamin D supplements if they do not get enough from their diet. Movymia can be used for up to two years. The two-year course of Movymia should be given only once during a patient's lifetime.

The medicine can only be obtained with a prescription.

How does Movymia work?

Osteoporosis happens when not enough new bone grows to replace the bone that is naturally broken down. Gradually, the bones become less dense and more likely to break. In women, osteoporosis is more common after the menopause, when the levels of the female hormone oestrogen fall. Osteoporosis can also occur as a side effect of glucocorticoid treatment in men and women.

The active substance in Movymia, teriparatide, is identical to part of the human parathyroid hormone. It acts like the hormone to stimulate bone formation by acting on osteoblasts (bone-forming cells). It also increases the absorption of calcium from food and prevents too much calcium being lost in the urine.

What benefits of Movymia have been shown in studies?

Laboratory studies comparing Movymia with Forsteo have shown that the active substance in Movymia is highly similar to that in Forsteo in terms of structure, purity and biological activity.

Because Movymia is a biosimilar medicine, the studies on effectiveness and safety of teriparatide carried out with Forsteo do not need to be repeated for Movymia. A study in 54 healthy women has shown that the same doses of the two medicines given by injection under the skin produced similar levels of the active substance teriparatide in the body. Further, Movymia and Forsteo produced similar effects on calcium levels in the blood.

What are the risks associated with Movymia?

The most common side effect with Movymia (seen in more than 1 patient in 10) is pain in the arms or legs. For the full list of all side effects reported with Movymia, see the package leaflet.

Movymia must not be used in patients who have other bone diseases such as Paget's disease, bone cancer or bone metastases (cancer that has spread to the bone), patients who have had radiation therapy of the skeleton, or patients who have hypercalcaemia (high blood calcium levels), unexplained high levels of alkaline phosphatase (an enzyme) or severe kidney disease. Movymia must not be used during pregnancy or breastfeeding. For the full list of restrictions, see the package leaflet.

Why is Movymia approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) considered evidence showing that Movymia has a highly similar structure, purity and biological activity to Forsteo and is distributed in the body in the same way. This was considered sufficient to conclude that Movymia will behave in

the same way in terms of effectiveness and safety. Thus, as for Forsteo, the benefit outweighs the identified risks and the Committee recommended that Movymia be given marketing authorisation.

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

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

Other information about Movymia

The European Commission granted a marketing authorisation valid throughout the European Union for Movymia on 11 January 2017.

The full EPAR for Movymia 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 Movymia, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2017.