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# Qutavina (*teriparatide*)

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



## What is Qutavina and what is it used for?

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

- women who have been through the menopause;
- 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).

Qutavina is a 'biosimilar medicine'. This means that Qutavina is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Qutavina is Forsteo. For more information on biosimilar medicines, see here.

Qutavina contains the active substance teriparatide.

## How is Qutavina used?

Qutavina is available in pre-filled pens as a solution for injection under the skin. The recommended dose is 20 micrograms of Qutavina injected once a day under the skin of the thigh or belly. Patients may inject themselves once they have been trained.

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

The medicine can only be obtained with a prescription. For more information about using Qutavina, see the package leaflet or contact your doctor or pharmacist.

## How does Qutavina 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.

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The active substance in Qutavina, 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 Qutavina have been shown in studies?

Laboratory studies comparing Qutavina with Forsteo have shown that the active substance in Qutavina is highly similar to that in Forsteo in terms of structure, purity and biological activity. Studies have also shown that giving Qutavina produces similar levels of the active substance in the body to giving Forsteo.

Because Qutavina is a biosimilar medicine, the studies on effectiveness and safety of teriparatide carried out with Forsteo do not all need to be repeated for Qutavina.

## What are the risks associated with Qutavina?

The safety of Qutavina has been evaluated, and on the basis of all the studies carried out the side effects of the medicine are considered to be comparable to those of the reference medicine Forsteo.

The most common side effect with teriparatide (seen in more than 1 patient in 10) is pain in the arms or legs; nausea (feeling sick), headache and dizziness are also common. For the full list of side effects of Qutavina, see the package leaflet.

Qutavina 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 that can be a sign of bone disease) or severe kidney disease. Qutavina must not be used during pregnancy or breastfeeding. For the full list of restrictions, see the package leaflet.

## Why is Qutavina authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Qutavina has a highly similar structure, purity and biological activity to Forsteo and is distributed in the body in the same way.

All these data were considered sufficient to conclude that Qutavina will behave in the same way as Forsteo in terms of effectiveness and safety in its authorised uses. Therefore, the Agency's view was that, as for Forsteo, the benefits of Qutavina outweigh the identified risks and it can be authorised for use in the EU.

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

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

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

## Other information about Qutavina

Qutavina received a marketing authorisation valid throughout the EU on 27 August 2020.

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

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