European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

FORCALTONIN

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. . If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Forcaltonin?
Forcaltonin is a clear solution for injection. Each ampoule contains 100 IU (International Units) of the active substance salmon calcitonin.

What is Forcaltonin used for?
Forcaltonin is used in adults to prevent bone loss due to sudden immobilisation such as in patients with recent bone fractures caused by osteoporosis (a disease that makes bones fragile). It is also used in Paget's disease (a bone disease that involves bone destruction and regrowth that causes deformity), and in hypercalcaemia (increased blood calcium) caused by cancer. Forcaltonin can only be obtained with a prescription.

How is Forcaltonin used?
Forcaltonin is given by subcutaneous injection (under the skin), intramuscular injection (into a muscle) or intravenous infusion (drip into a vein – only in hypercalcaemia). The doses and duration of treatment depend on to the patient's response to the medicine.
To prevent bone loss, the recommended dosage is 100 IU daily or 50 IU twice daily for 2 to 4 weeks, given subcutaneously or intramuscularly.
In Paget's disease, the recommended dosage is 100 IU per day given subcutaneously or intramuscularly, however, a minimum dose of 50 IU three times a week is also effective.
In hypercalcaemia, the recommended starting dose is 100 IU every 6 to 8 hours by subcutaneous or intramuscular injection. This may be increased after one or two days, according to the patient's response to treatment, up to a maximum of 400 IU every 6 to 8 hours. In severe or emergency cases, Forcaltonin may be given as an intravenous infusion (10 IU per kg body weightover 6 hours).

How does Forcaltonin work?
Forcaltonin contains the active ingredient salmon calcitonin, which works in the same way as natural human calcitonin but it is more effective and longer lasting. Calcitonin is a hormone produced by the thyroid gland that increases the amount of calcium and phosphorus laid down in the bones and lowers the level of calcium circulating in the blood. Salmon calcitonin, either extracted from salmon or synthetic (man-made), has been in use as a medicine since the mid-1970s. The active substance of Forcaltonin, salmon calcitonin, is a copy of the hormone produced by a method known as 'recombinant DNA technology': it is made by a cell that has received a gene (DNA), which makes it able to produce salmon calcitonin.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 16
E-mail: mail@emea.eu.int http://www.emea.eu.int

How has Forcaltonin been studied?
Because salmon calcitonin has been in use for some time, the company presented data to show that Forcaltonin has been compared with synthetic salmon calcitonin. This included the results of three studies of the effectiveness and safety of Forcaltonin in 94 women, including 58 with osteoporosis. These studies measured the markers of bone metabolism.

What benefit has Forcaltonin shown during the studies?
Forcaltonin showed the same effectiveness and safety profile as synthetic salmon calcitonin.

What is the risk associated with Forcaltonin?
The most common side effect found in about 10% of patients is nausea (feeling sick) with or without vomiting. This side effect is more likely at the start of treatment and tends to decrease or disappear with further doses or smaller doses. This side effect is less common when the injection is given in the evening and after meals. Other common side effects are skin flushes (face or upper body). For the full list of side effects reported with Forcaltonin, see the Package Leaflet.
Forcaltonin should not be used in people who have hypocalcaemia (low calcium levels in the blood) or who may be hypersensitive (allergic) to calcitonin or any of the other ingredients. The doctor may decide to perform a skin test to check the patient's allergy status before prescribing the medicine.

Why has Forcaltonin been approved?
The Committee for Medicinal products for Human Use (CHMP) concluded that Forcaltonin had been shown to have the same characteristics and properties as synthetic salmon calcitonin. They decided that Forcaltonin's benefits are greater than its risks for prevention of bone loss due to sudden immobilisation, such as in patients with recent bone fractures caused by osteoporosis (a disease that makes bones fragile), for treatment of Paget's disease, and treatment of hypercalcaemia of malignancy. They recommended that Forcaltonin be given marketing authorisation.

Other information about Forcaltonin:
The European Commission granted a marketing authorisation valid throughout the European Union, for Forcaltonin to Unigene UK Limited on 11 January 1999. The marketing authorisation was renewed on 4 July 2004.

The full EPAR for Forcaltonin is available here.

This summary was last updated in 06-2006.