



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency recommends limiting long-term use of calcitonin medicines

Intranasal formulation for osteoporosis treatment to be withdrawn; new restriction to indication for injectable use in Paget's disease.

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended that calcitonin-containing medicines should only be used for short-term treatment, because of evidence that long-term use of these medicines is associated with an increased risk of cancer.

Doctors should no longer prescribe calcitonin-containing medicines as nasal spray for the treatment of osteoporosis.

Calcitonin will only be available as a solution for injection and infusion, and should only be used for:

- prevention of acute bone loss due to sudden immobilisation, with treatment recommended for two weeks with a maximum duration of four weeks;
- Paget's disease in patients who do not respond to alternative treatments or for whom such treatments are not suitable, with treatment normally limited to three months;
- hypercalcaemia caused by cancer.

Treatment with calcitonin should be limited to the shortest possible time and using the minimum effective dose.

Analysis of all available calcitonin trials showed an increased risk of cancer. In long-term clinical trials the risk of developing cancer was 0.7% to 2.4% higher in patients receiving calcitonin-containing medicines compared to those patients receiving placebo, with the higher rates seen in trials with intranasal calcitonin.

Taking into account the limited efficacy of calcitonin when used to treat post-menopausal osteoporosis to reduce the risk of vertebral fractures, the CHMP concluded that the benefits of calcitonin-containing medicines did not outweigh their risks in this indication. As the nasal spray is only used in osteoporosis, the CHMP recommended that this formulation be withdrawn.



For all other approved indications the CHMP considered that the benefit-risk balance remains positive, but recommended that calcitonin treatment should be given for the shortest possible time. For the treatment of patients with Paget's disease, the CHMP also recommended to limit the use of calcitonin to a second-line indication in patients who do not respond to alternative treatments or for whom such treatments are not suitable. Treatment in this condition should normally be limited to 3 months; however, it may be extended to 6 months in exceptional circumstances, and intermittently repeated if it is considered that the potential benefits outweigh the risks.

The CHMP's opinion is being forwarded to the European Commission for the adoption of a decision.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. A question-and-answer document with more information is available on the Agency's website.
3. More information on the work of the European Medicines Agency can be found on its website:
www.ema.europa.eu

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