Withdrawal of Miacalcic® nasal spray and recommendations to limit the long-term use of calcitonin medicines

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Information on Calcitonin

Calcitonin is a hormone that increases the amount of calcium in the bones and lowers the calcium level in the blood. Calcitonin is used in medicines which treat or prevent conditions that involve the loss of calcium from the bones mainly:

- Osteoporosis (a disease that makes bones fragile)
- Paget's disease (a bone disease that involves bone remodelling and can cause deformity), and
- Hypercalcaemia (increased blood calcium) caused by cancer
- To prevent acute bone loss due to sudden immobilisation such as in patients with recent osteoporotic fractures.

Calcitonin-containing medicines are available in Malta as a solution for injection and as a nasal spray and are used in hospitals only.

Information from European Medicines Agency about the safety concern

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has analysed the data from calcitonin trials and found an increased risk of cancer especially in the long-term clinical trials where the risk of developing cancer was 0.7% to 2.4% higher in patients receiving calcitonin-containing medicines compared to those patients receiving placebo. The higher rates were 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. Therefore the

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CHMP recommended that the nasal spray which is only used in the osteoporosis indication should be withdrawn.

While the benefit-risk balance remains positive for the solution for injection the CHMP recommended that calcitonin-containing medicines should only be used for short-term treatment.

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

In Malta

For Healthcare Professionals

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 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; 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.
- hypercalcaemia caused by cancer.

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

For more information please see the **question-and-answer** document issued by the European Medicines Agency.

For Patients

- Calcitonin will no longer be used for the treatment of osteoporosis. Patients being treated for osteoporosis with calcitonin nasal sprays or other formulations are advised to speak to their doctor at a routine appointment, who will recommend suitable alternative treatment.

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- Patients receiving injectable calcitonin who have any questions should speak to their doctor or pharmacist.

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on Calcitonon-containing medicinal products. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority yellow card scheme or online at **http://www.medicinesauthority.gov.mt/adrportal** the marketing authorisation holder or their local representatives.

Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

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