DIPARTIMENT TAS-SAĦĦA DEPARTMENT OF HEALTH
MALTA

L-Uffiċċju tal-Uffiċjal Mediku Ewlieni *Office of the Chief Medical Officer*

DH CIRCULAR No. 89/2014
DH 1223/2014

13th March 2014

Attention All: Consultants
Medical Officers
Pharmacists
Pharmacy Technicians
Nurses

Re: Recommendations to limit the long-term use of calcitonin injections

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) 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.

An analysis carried out by CHMP on the data from calcitonin trials 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.

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

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

- prevention of acute bone loss due to sudden immobilization, with treatment recommended for two weeks with a maximum 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 smallest effective dose.

For more information please see the 'questions and answers on the review of calcitonin-containing medicines document' issued by the European Medicines Agency available at: http://www.ema.europa.eu/docs/en_GB/document_library/Referrals_document/Calcitonin_31/WC500130149.pdf

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Healthcare professionals should report any suspected side effects of calcitonin injections via the National Adverse Drug Reaction (ADRs) reporting system. Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and posted to Medicines Authority Post-Licensing Directorate or sent by email to postlicensing.medicinesauthority@gov.mt.

Calcitonin 100IU/ml injections are available on the Government Formulary List (GFL). The GFL has been updated to reflect the CHMP recommendations.

For your attention please

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A/Chief Medical Officer