

衛生署藥物辦公室
藥物註冊及進出口管制部

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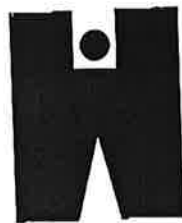
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Dr. Raymond LIANG
President
Hong Kong Academy of Medicine
(Fax Number: 2505 5577)



DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG REGISTRATION AND
IMPORT/EXPORT CONTROL DIVISION
3/F., Public Health Laboratory Centre,
382 Nam Cheong Street, Kowloon, Hong Kong

BY FAX

23 July 2012

Dear Dr. LIANG,

EMA : Recommendations on limiting long-term use of calcitonin medicines

Please kindly note that 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.

EMA advised that calcitonin-containing medicines as nasal spray should no longer be prescribed 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.

Please refer to EMA's website for details:


http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2012/07/news_detail_001573.jsp&mid=WC0b01ac058004d5c1

In Hong Kong, there are 4 registered pharmaceutical products containing calcitonin and are prescription-only medicines. 2 of them are nasal spray products, namely Miacalcic Nasal Spray 200iu (HK-43614) and Apo-Calcitonin Nasal Spray 200iu/spray (HK-58746). They are indicated for osteoporosis and Miacalcic Nasal Spray 200iu (HK-43614) is also indicated for bone pain associated with osteolysis and/or osteopenia, Paget's disease and neurodystrophic disorders. Miacalcic Inj 100iu/ml (HK-27880) and Miacalcic Inj 50iu/ml (HK-28413) are injection products. They are indicated for osteoporosis, bone pain associated with osteolysis and/or osteopenia, Paget's disease, neurodystrophic disorders, hypercalcaemia and adjuvant therapy of acute pancreatitis. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment. In view of the EMA's recommendation, the matter will be discussed in the meeting of Registration Committee of the Pharmacy and Poisons Board.

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Please report any adverse events caused by the drugs to the Pharmacovigilance Unit of Department of Health (tel. no.: 2319 2920, fax: 2147 0457 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": <http://www.drugoffice.gov.hk/adr.html>. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly drug safety digest of drug safety news and information issued by Drug Office.

Yours faithfully,


(Ms. Lilly)^{HO}
for AD(D)

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