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Deregistration and Recall of Miacalcic Nasal Spray and safety changes to Miacalcic 100 IU/ml solution for injection or infusion

Dear Healthcare Professional,

Summary

Concerns of a possible association between calcitonin and prostate cancer have been raised and considered at different times. However, review of available data at the time by National Competent Authorities did not indicate a causal relationship. The issue was however kept under close monitoring.

On the basis of this new safety information the UK requested the opinion of the Committee for Medicinal Products for Human Use (CHMP), under Article 31 of Directive 2001/83/EC whether the marketing authorisations for medicinal products containing calcitonin should be maintained, varied, suspended or withdrawn. Miacalcic Nasal Spray will be recalled from the market.

Miacalcic Nasal Spray

The Committee concluded that the benefit-risk balance of calcitonin-containing intranasal formulation indicated for the treatment of osteoporosis is no longer positive under normal conditions of use and recommends the suspension of the corresponding marketing authorisations.

Novartis Pharma Malta has applied for the deregistration of Miacalcic Nasal Spray with the proposed date of withdrawal of 1st April 2013.

This product is being recalled upto pharmacy level and all batches will be collected from the market by the 5th April 2013.

Miacalcic 100 IU/ml solution for injection

On 13 Feb 2013, the EC decision for the Miacalcic Article 31 referral had been finalized.
In order to maintain a positive benefit/risk balance for the indications of injectable formulation of calcitonin-containing products, the CHMP recommended changes to the Product Information, mainly in relation to the risk of cancer.

Amendments to the relevant sections of the Summary of Products Characteristics (SmPC):

4.1 Therapeutic indications
4.2 Posology and method of administration
4.4 Special warnings and precautions for use
4.8 Undesirable effects

Amendments to the relevant sections of the Patient Information Leaflet (PIL):

1. What Miacalcic solution for injection or infusion is and what it is used for
2. Before you start treatment with Miacalcic solution for injection or infusion
3. How Miacalcic solution for injection or infusion is used
4. Possible side effects

The content of this letter has been agreed with the Medicines Authority.

Call for Reporting

Healthcare professionals should report any suspected adverse reactions associated with use of Miacalcic (See below).

Suspected adverse drug reaction should be reported to the Malta Medicines Authority by use of postlicensing.medicinesauthority@gov.mt. Alternatively any suspected adverse reactions can also be reported to Medicines Authority Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gzira GZR 1368, MALTA, or at: http://www.medicinesauthority.gov.mt/pub/adrportal.

Adverse reactions should also be reported to Novartis on 22983217 / 21222872 or drug_safety.malta@novartis.com.

Yours sincerely,

Graziella Vella