

**Safeguarding public health  
Defective Medicines Report Centre  
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**MHRA**

# **DRUG ALERT**

## **CLASS 2 MEDICINES RECALL**

**Action Within 48 Hours  
Pharmacy, Clinic and Wholesaler Level Recall**

Date: 02 April 2013

EL 13(A)11

Our Ref: MDR 42-03/13

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Dear Healthcare Professional,

### **Novartis Pharmaceuticals UK Ltd**

#### **Miacalcic 200 IU Nasal Spray Solution**

**PL 00101/0586**

#### **Calcitonin (salmon)**

All unexpired stock of this product is being recalled to pharmacy, clinic and wholesaler level irrespective of batch number and expiry date.

The product is being withdrawn throughout the European Union after a study has shown an increased risk of malignancies with the long term use of calcitonin. Both the Committee for Medicinal Products for Human Use (CHMP) and the Pharmacovigilance Risk Assessment Committee have concluded that the benefits no longer outweigh the risks.

No further Miacalcic 200 IU Nasal Spray Solution should be dispensed. Pharmacists should refer patients with new or repeat prescriptions to the treating physician to review their treatment plan on a non-urgent basis.

Remaining stocks of the affected batches should be quarantined and returned to the original supplier for credit. For enquiries relating to stock returns please contact Novartis Pharmaceuticals Customer Care team on 08457-419442 or email [novartis.customercare@novartis.com](mailto:novartis.customercare@novartis.com).

For medical information enquiries please contact Novartis Pharmaceuticals UK Ltd Medical Information on 01276 698370 or email [medinfo.uk@novartis.com](mailto:medinfo.uk@novartis.com).

Contd/...

#### **MHRA Distribution:**

Regional Contacts for NHS Trusts and Provider Units  
Chief Pharmacists: England, Scotland, Wales, Northern Ireland  
Prison Health Policy Unit (DH)  
Chief Pharmacists: Jersey, Guernsey, Alderney, Sark, Isle of Man, Gibraltar  
Special Hospitals  
Healthcare Commission for distribution to Independent Health Care Establishments  
Primary Care Trusts (England)

**Medicines and Healthcare products Regulatory Agency (MHRA)**  
151 Buckingham Palace Road London SW1W 9SZ UK  
T 020 3080 6000 [www.mhra.gov.uk](http://www.mhra.gov.uk)

An executive agency of the Department of Health



Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. Primary Care Trusts are asked to forward this to relevant clinics, General Practitioners and Community Pharmacists for information.

Yours faithfully  
Adam Burgess  
MHRA DMRC Manager