July 31, 2013

Dear Health Care Professional,

**Subject:** Market Withdrawal of all synthetic calcitonin (salmon) Nasal Spray (NS) Products, effective October 1st, 2013

- MIACALCIN® NS, DIN 02240775 (Novartis Pharmaceuticals Canada Inc.)
- SANDOZ CALCITONIN NS DIN 02261766 (Sandoz Canada Inc.)
- APO-CALCITONIN NS DIN 02247585 (Apotex Inc.)

The manufacturers of **synthetic calcitonin (salmon) Nasal Spray (NS) Products** (listed above), in collaboration with Health Canada, would like to advise you of the market withdrawal of these Products, effective October 1st, 2013.

All three products are authorized in Canada for the treatment of postmenopausal osteoporosis in females greater than five years post menopause with low bone mass relative to healthy premenopausal females.

- Following the review of safety and efficacy information for synthetic calcitonin (salmon) nasal spray products, Health Canada has concluded, in light of a newly identified risk of malignancies (cancer), that its benefit-risk profile for the treatment of postmenopausal osteoporosis is no longer considered favourable.
- As a result of these findings, calcitonin (salmon) nasal spray will be withdrawn from the market effective October 1st, 2013.
- Patients being treated for osteoporosis with synthetic calcitonin (salmon) should be switched to an alternative treatment.

Health Canada has evaluated information on the risk of malignancies from randomised controlled trials in patients with osteoporosis or osteoarthritis receiving calcitonin (salmon) nasal spray or an unlicensed oral calcitonin formulation. Patients treated with calcitonin in these trials had a low but observable increased rate of malignancies compared with patients taking placebo. The increased rates seen with calcitonin compared to placebo varied between 0.7% in studies with the oral formulation to 2.4% in the studies with the nasal formulation. Taking this new safety information and the available efficacy data into account, Health Canada concluded that the risks of calcitonin (salmon) nasal spray outweigh the benefits for the treatment of established post-menopausal osteoporosis.

As of July 3, 2013, the manufacturers cited above have ceased the sale of **synthetic calcitonin (salmon) Nasal Spray (NS) Products**. Distribution of the products will be phased out and the DINs for the above-cited products will be cancelled on October 1st, 2013.
Healthcare professionals should no longer prescribe the above-mentioned products for the treatment of osteoporosis and are advised to seek alternative therapies for their patients. Pharmacists are advised that dispensing should cease by October 1st, 2013, since the DINs will become inactive on that date. To ensure full inventory depletion, we advise that the above-cited products be removed from your inventory by October 1st, 2013. Pharmacists wishing to return remaining unused product by that date may do so by returning to their wholesaler for a refund. Patients being treated for osteoporosis with any of the above-mentioned products are advised to speak to their doctor for a recommendation of suitable alternative treatment.

Managing marketed health product-related adverse reactions depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse reactions are generally presumed to underestimate the risks associated with health product treatments. Any case of serious overdose symptoms or other serious or unexpected adverse reactions in patients receiving calcitonin NS should be reported to the respective product manufacturer or Health Canada at the following addresses:

**MIACALCIN® NS**
Novartis Pharmaceuticals Canada Inc.
385 Bouchard blvd,
Dorval, Quebec, H9S 1A9
Phone: 1-800-363-8883 (Medical Information), Fax:514-636-3175

**SANDOZ CALCITONIN NS**
Sandoz Canada Inc.
145, Jules-Leger,
Boucherville, Quebec, J4B 7K8
Phone: 1-800-361-3062 (Drug Information)

**APO-CALCITONIN NS**
Apopex Inc.,
150 Signet Drive,
Toronto, Ontario M9L 1T9
Phone: 1-800-667-4708 (Drug Safety), Fax: 1-416-401-3819 Email: drugsafety@apotex.com

To change your mailing address or fax number, please contact Healthcare Advisor by fax at 1-866-825-7101 or by e-mail at healthcareadvisor@plexus360.com.

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:
- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada’s Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax

**For other health product inquiries related to this communication, please contact Health Canada at:**
Marketed Health Products Directorate (MHPD)
E-mail: MHPD_DPSC@hc-sc.gc.ca
Tel: 613-954-6522
Fax: 613-952-7738

Should you have any questions or require additional information regarding the use of calcitonin NS, please contact the respective manufacturer
- for MIACALCIN® NS - Novartis Pharmaceuticals Canada Inc., Medical Information Department at 1-800-363-8883,
- for SANDOZ CALCITONIN NS, Sandoz Canada Inc., Drug Information Department at 1-800-361-3062 and
- for APO-CALCITONIN NS Apotex Drug Information at 1-800-667-4708.
Sincerely,

Original signed by

Jean Godin, M.D.
Chief Scientific Officer and Vice President, Clinical and Regulatory Affairs
Novartis Pharmaceuticals Canada Inc.

Original signed by

Len Arsenault
Vice-President, Scientific Affairs
Sandoz Canada Inc.

Original signed by

Colin D’Cunha MBBS, MHSc, FRCPC
Director-Global Medical Affairs, Apotex Inc.