NOVARTIS

IMPORTANT DRUG SAFETY INFORMATION

SUBJECT: Foradil*(formoterol fumarate) Aerolizer* Dry Powder Capsules for Inhalation Safety Update

September 7, 2005

Dear Health Care Professional:

Novartis Pharmaceuticals Canada Inc. ("Novartis"), in consultation with Health Canada would like to inform you of the outcome of the recent U.S. Food and Drug Administration's Pulmonary-Allergy Drugs Advisory Committee (PADAC) meeting held on July 13, 2005, to discuss the implications of recently available data related to the safety of long-acting $ß_2$ agonist bronchodilators, which includes Novartis' Foradil* (formoterol fumarate) and GlaxoSmithKline's Serevent® (salmeterol) and Advair® (salmeterol & fluticasone propionate).

The data from a large placebo-controlled US study (SMART - the Salmeterol Multi-Center Asthma Research Trial) that compared the safety of salmeterol or placebo-added to patients' usual asthma therapy showed increased risks of asthma-related death and other serious respiratory-related outcomes in patients who used salmeterol. *Post hoc* analysis of the data suggests that the risks may be greater in patients who did not report using inhaled corticosteroid at study entry and in African-American patients. Although available data for formoterol do not suggest increased risk, the Advisory Committee could not exclude that the risk may apply to all long-acting $ß_2$ agonists including formoterol.

However, the committee unanimously agreed that formoterol and salmeterol should continue to be commercially available as treatment option for patients with asthma.

The review of the safety of formoterol is ongoing at Health Canada and further action may be taken if necessary.

Important Advice for Managing Your Patients

Novartis believes it is important to reiterate and reinforce advice for the management of patients established in the Canadian Asthma Consensus Guidelines and prescribing information for Foradil* (formoterol fumarate) Aerolizer*:

- Patients with asthma should be receiving optimal anti-inflammatory therapy with corticosteroids before starting maintenance therapy with Foradil*.
- Foradil* is not a replacement for inhaled or oral corticosteroids. Patients must be warned not to stop or reduce corticosteroid therapy without medical advice.
- Foradil* should not be initiated in patients with significantly worsening or acutely deteriorating asthma, which is a potentially life-threatening condition.
- Foradil* should not be used to treat acute asthma symptoms.
- Patients who are currently taking Foradil* should not discontinue their treatment without first consulting a physician. Abruptly stopping medications may result in acutely deteriorating asthma control, which may be life-threatening
- Foradil* should be used at the lowest effective dosage (and re-assessed as needed), as recommended by the treating physician.
- Patients on Foradil* must also have a short-acting bronchodilator (e.g., salbutamol) for use as needed for acute symptoms.
- The increased need for using the short-acting bronchodilator is a sign of deteriorating asthma.

- Patients should be educated to recognize the signs of deteriorating asthma control and the need to seek medical attention promptly in such circumstances.

Novartis is fully committed to assuring timely dissemination of safety information about our products to the healthcare community. We appreciate your continued participation in our ongoing efforts to collect additional information on the safety and efficacy of Foradil*, and trust that the above-mentioned information will be of assistance to you. The identification, characterization, and management of marketed health product-related adverse events are dependent on the active participation of health care professionals in adverse drug reaction reporting programmes. Any occurrences of serious and\or unexpected adverse events in patients also receiving Foradil* should be reported to:

Novartis Pharmaceuticals Canada Inc.
385 Bouchard blvd,
Dorval, (QC) H9S 1A9
Phone:1-800-363-8883 (Medical Information)

Any suspected adverse reaction can also be reported to:
Canadian Adverse Drug Reaction Monitoring Program (CADRMP)
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0701C
OTTAWA, Ontario, K1A 0K9
Tel: (613) 957-0337 or Fax: (613) 957-0335
To report an Adverse Reaction, consumers & health professionals may call toll free: Tel: 866 234-2345
Fax: 866 678-6789
cadrmp@hc-sc.gc.ca

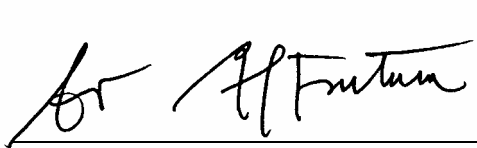
The AR Reporting Form (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/form/index_e.html) and the AR Guidelines (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/guide/index_e.html) can be found on the Therapeutic Products Directorate web site or in The Canadian Compendium of Pharmaceuticals and Specialties.

Novartis is committed to working with health authorities to ensure the Foradil* Product Monograph and Prescribing Information provides physicians and patients the information they need to treat asthma safely and effectively.

Should you have any questions or require additional information regarding the use of Foradil* (formoterol fumarate) Aerolizer*, please contact Novartis Pharmaceuticals Canada Inc., Medical Information at 1-800-363-8883 from 8:30 AM to 4:30 PM Monday to Friday Eastern Standard Time.

Sincerely,

Pier-Giorgio Fontana, Ph.D.
Vice-President, Drug Regulatory Affairs



Jean-Marie Leclerc, M.D. FRCP (c)
Chief Scientific Officer and
Senior Vice President, Clinical and
Regulatory Affairs

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