NOVARTIS

IMPORTANT DRUG WARNING

December 19, 2011

Subject: Important information in the ARCAPTA™ NEOHALER™ Prescribing Information—regarding safety of long-acting beta$_2$-agonists.

Dear Healthcare Professional:

Novartis Pharmaceuticals Corporation would like to inform you of important safety information contained in the package insert for ARCAPTA™ NEOHALER™ (indacaterol inhalation powder).

ARCAPTA NEOHALER is a long-acting beta$_2$-agonist (LABA) indicated for the long-term, once-daily maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

New important safety information related to ARCAPTA NEOHALER includes:

- Increased risk of asthma-related death in patients taking LABAs for treatment of asthma.
- New prescribing guidelines.

ARCAPTA NEOHALER is indicated for use in adults with COPD including chronic bronchitis and emphysema. ARCAPTA NEOHALER is NOT indicated to treat asthma.

ARCAPTA NEOHALER has a risk evaluation and mitigation strategy (REMS) that consists of a communication program.

The ARCAPTA NEOHALER Prescribing Information includes a boxed warning highlighting an increased risk of asthma-related deaths observed in patients taking LABAs for the treatment of asthma.

WARNING: ASTHMA-RELATED DEATH

Long-acting beta$_2$-adrenergic agonists (LABA) increase the risk of asthma-related death. Data from a large placebo-controlled US study that compared the safety of another long-acting beta$_2$-adrenergic agonist (salmeterol) or placebo added to usual asthma therapy showed an increase in asthma-related deaths in patients receiving salmeterol. This finding with salmeterol is considered a class effect of LABA, including indacaterol, the active ingredient in ARCAPTA NEOHALER. The safety and efficacy of ARCAPTA NEOHALER in patients with asthma have not been established. ARCAPTA NEOHALER is not indicated for the treatment of asthma. [See Contraindications (4), Warnings and Precautions (5.1)].

See the full Prescribing Information for a more complete description. References within the boxed warning refer to sections within the full Prescribing Information.

arcapta™
neohaler™
(indacaterol inhalation powder)

Please note that ARCAPTA NEOHALER should not be initiated in patients with acutely deteriorating COPD, which may be a life-threatening condition. The use of ARCAPTA NEOHALER in this setting is inappropriate.

ARCAPTA NEOHALER should not be used in conjunction with other inhaled, long-acting beta$_2$-agonists. ARCAPTA NEOHALER should not be used with other medications containing long-acting beta$_2$-agonists.

When beginning treatment with ARCAPTA NEOHALER, patients who have been taking inhaled, short-acting beta$_2$-agonists on a regular basis (e.g., four times a day) should be instructed to discontinue the regular use of these drugs and use them only for symptomatic relief of acute respiratory symptoms.

ARCAPTA NEOHALER is not indicated for the relief of acute bronchospasm.

Please instruct patients to contact you if breathing problems worsen over time while using ARCAPTA NEOHALER and get emergency medical care if breathing problems worsen quickly and are not being relieved by the use of the rescue inhaler.

ARCAPTA NEOHALER should not be used in children as the safety and efficacy of ARCAPTA NEOHALER have not been established in pediatric patients.

Please take time to read the enclosed ARCAPTA NEOHALER Package Insert for full prescribing information, for complete description of this important safety information and the prescribing guidelines.

To report adverse events potentially associated with ARCAPTA NEOHALER, please call Novartis Pharmaceuticals Corporation at 1-888-NOW-NOVA (1-888-669-6682).

Alternatively, adverse event information may be reported to FDA's MedWatch Reporting System by:

- Phone at 1-800-FDA-1088 (1-800-332-1088)
- Facsimile at 1-800-FDA-0178 (1-800-332-0178)
- Mail using FDA Form 3500 located at http://www.fda.gov/medwatch

Please contact Novartis at 1-888-NOW-NOVA (1-888-669-6682) or go to http://www.arcapta.com if you have any questions about ARCAPTA NEOHALER or this information.

Sincerely,

James Williams, MD
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Novartis Pharmaceuticals Corporation