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Dear Healthcare Professional:

Dey Pharma, L.P. would like to inform you of important safety-related changes to the PERFOROMIST[®] (formoterol fumarate) Inhalation Solution, 20 mcg/2mL prescribing information.

PERFOROMIST[®] is a long-acting beta₂-adrenergic agonist (LABA) indicated for long-term, twice daily (morning and evening) administration in the maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

New important safety information related to PERFOROMIST[®] includes:

- Increased risk of asthma-related death in patients taking LABAs for treatment of asthma.
- New prescribing guideline.
 - All LABA, including PERFOROMIST[®], are contraindicated in patients with asthma without the concomitant use of a long term asthma controller medication.

PERFOROMIST[®] is indicated for use in adults with COPD including chronic bronchitis and emphysema.

PERFOROMIST[®] is not indicated for the treatment of asthma.

PERFOROMIST[®] has a risk evaluation and a mitigation strategy (REMS) that consists of a Medication Guide and a communication program.

The PERFOROMIST[®] labeling includes a boxed warning to highlight the safety issue of asthma-related death.

WARNING: ASTHMA-RELATED DEATH

Long-acting beta₂-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 beta₂-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 formoterol, the active ingredient in PERFOROMIST Inhalation Solution. The safety and efficacy of PERFOROMIST in patients with asthma have not been established. All LABA, including PERFOROMIST, are contraindicated in patients with asthma without use of a long-term asthma control medication (see CONTRAINDICATIONS, WARNINGS, AND PRECAUTIONS in the Prescribing information).

Please note that PERFOROMIST[®] Inhalation Solution should not be initiated in patients with acutely deteriorating COPD, which may be a life-threatening condition. The use of PERFOROMIST[®] in this setting is inappropriate.

When prescribing PERFOROMIST[®], please also provide the patient with an inhaled, short-acting beta₂-agonist for treatment of COPD symptoms that occur acutely.

PERFOROMIST[®] should not be used in conjunction with other inhaled, long-acting beta₂-agonists.
PERFOROMIST[®] should not be used with other medications containing long-acting beta₂-agonists.

When beginning treatment with PERFOROMIST[®], patients who have been taking inhaled, short-acting beta₂-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.

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

Please take time to read the enclosed PERFOROMIST[®] Package Insert for full prescribing information, for complete description of this important safety information and the new prescribing guidelines.

PERFOROMIST[®] is not indicated for use in children. The safety and efficacy of PERFOROMIST[®] in pediatric patients have not been established.

In addition, please review the attached Medication Guide with each patient who is prescribed PERFOROMIST[®].

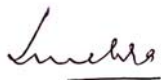
The Medication Guide will be enclosed in each carton packaging and must be provided by the authorized dispensers to each patient to whom the drug is dispensed.

To report adverse events potentially associated with PERFOROMIST[®] please call 1-800-395-3376. 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 Dey Medical Information at 1-800-429-7751 if you have any questions about PERFOROMIST[®] or the information in this letter.

Sincerely,



Sunil Mehra, MD, FRCP, FAAAAI
Chief Medical Officer
Dey Pharma, L.P.