

April 9, 2008

Dear Dr [insert Doctor Name]

Re: EXUBERA® (insulin human [rDNA origin] Inhalation Powder) Labeling update

In keeping with Pfizer's continued commitment to share with health care providers important information regarding EXUBERA, we are providing the following update to the labeling.

Prescribing Information Update

The EXUBERA label was updated by Pfizer and FDA. The update resulted from Pfizer and FDA's ongoing safety reporting and review processes related to our clinical trials program and post-marketing reports. A new WARNING was added to the EXUBERA prescribing information as follows:

WARNINGS

In clinical trials of Exubera, there have been 6 newly diagnosed cases of primary lung malignancies among Exubera-treated patients, and 1 newly diagnosed case among comparator treated patients. There has also been 1 post-marketing report of a primary lung malignancy in an Exubera-treated patient. In controlled clinical trials of Exubera, the incidence of new primary lung cancer per 100 patient-years of study drug exposure was 0.13 (5 cases over 3900 patient-years) for Exubera-treated patients and 0.02 (1 case over 4100 patient-years) for comparator-treated patients. There were too few cases to determine whether the emergence of these events is related to Exubera. All patients who were diagnosed with lung cancer had a prior history of cigarette smoking.

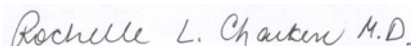
Exubera remains a safe and effective medication and this label update should support healthcare providers and patients in their discussions about EXUBERA. Some patients continue to take Exubera including those enrolled in the Extended Transition Program. Since there is limited availability of Exubera, physicians should seek alternate treatment options to maintain patients' glycemic control.

A "Dear Patient" letter and updated labeling will be sent to all patients in the EXUBERA Extended Transition Program. Patients will be advised to speak to their physician regarding this new information on EXUBERA.

We have enclosed a copy of the revised EXUBERA Prescribing Information and Medication Guide for your information.

For more information about EXUBERA, please contact Pfizer Medical Information at **1-800-438-1985**. We hope you find this information helpful in understanding this subject so you can continue to appropriately treat your patients.

Sincerely,



Rochelle L. Chaiken, MD
Vice President, Global Medical Cardiovascular and Metabolic Disease
Pfizer Inc
Encl: Updated Prescribing Information and Medication Guide

Other important safety information:

Exubera is a rapid-acting insulin indicated for the treatment of adults with diabetes mellitus for the control of hyperglycemia. In patients with type 1 diabetes, EXUBERA should be used in regimens that include a longer-acting insulin. In patients with type 2 diabetes, EXUBERA can be used as monotherapy or in combination with oral agents or longer-acting insulins.

EXUBERA is contraindicated in patients who smoke or who have discontinued smoking less than 6 months prior to starting EXUBERA therapy. If a patient starts or resumes smoking, EXUBERA must be discontinued immediately due to the increased risk of hypoglycemia and an alternative treatment must be utilized.

EXUBERA is contraindicated in patients with unstable or poorly controlled lung disease, because of wide variations in lung function that could affect the absorption of EXUBERA and increase the risk of hypoglycemia or hyperglycemia. The use of EXUBERA in patients with underlying lung disease, such as asthma or COPD, is not recommended because the safety and efficacy of EXUBERA in this population have not been established.

Hypoglycemia is the most commonly reported adverse event of insulin therapy, including EXUBERA

In clinical trials, treatment with EXUBERA was associated with small, non-progressive mean declines in pulmonary function relative to comparator treatments. Because of the effect of EXUBERA on pulmonary function, all patients should have pulmonary function tests (e.g., spirometry) assessed prior to initiating therapy with EXUBERA, after 6 months of therapy, and annually thereafter, even in the absence of pulmonary symptoms.

The long-term safety and effectiveness of EXUBERA in pediatric patients have not been established

In clinical studies, respiratory adverse events included cough, which tended to occur within seconds to minutes after EXUBERA inhalation. The incidence of cough decreased with continued EXUBERA use. Other respiratory adverse events included dyspnea, pharyngitis, sputum increase, and epistaxis. Non-respiratory adverse events reported in EXUBERA-treated patients include: hypoglycemia, chest pain, and dry mouth.