

Initial REMS approval: 01/ 2010

Most recent modification: 05/ 2011

NDA 22-341 VICTOZA[®] (liraglutide [rDNA origin] injection)

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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL

- To inform providers about the potential risk of medullary thyroid carcinoma and the risk of acute pancreatitis (including necrotizing pancreatitis) associated with VICTOZA[®].

II. REMS ELEMENTS

A. Communication Plan

Novo Nordisk will implement the following elements of a communication plan to healthcare providers (HCP) likely to prescribe VICTOZA[®] to support implementation of this REMS:

The communication plan will include:

*i. A **Reminder Dear HCP (DHCP) Letter for Primary Care Providers** addressing the potential risk of medullary thyroid tumors and the risk of acute pancreatitis and appropriate patient selection will be mailed to HCPs. The timing of the mailing will be within 60 days after approval of this REMS modification. The Reminder DHCP Letter will contain the FDA-approved labeling. The intended audience for this Reminder DHCP letter will be primary healthcare providers who are likely to prescribe VICTOZA[®] and others identified through professional organizations (e.g. AMA). These include physicians, nurse practitioners, and physicians' assistants, predominantly in the specialties of Internal Medicine and Family Practice. Any newly identified (through 3 years after product*

approval) primary care prescribers of VICTOZA[®] will be fully detailed on the contents of the Communication Plan.

In addition, the *Reminder Dear Healthcare Professional Letter for Primary Healthcare Providers* will be distributed by Novo Nordisk representatives during the first discussion of VICTOZA[®] with all primary care providers visited during the first six months after approval of this REMS modification. The Novo Nordisk representative will discuss the risk message contained in the DHCP letter with the primary care provider visited.

Please see the appended *Reminder Dear Healthcare Professional Letter for Primary Healthcare Providers*.

ii. A Direct Mail Letter containing the information included in the DHCP letter will also be mailed once per year, beginning 6 months following dissemination of the Reminder DHCP Letter for Primary Care Providers for a total of 3 years following approval of this REMS modification to all prescribers who are likely to prescribe VICTOZA[®].

Please see the appended *Direct Mail Letter*.

In addition, Novo Nordisk will send the DHCP Letter and the Direct Mail Letter to MedWatch at the same time the letters are disseminated to the target audience.

Novo Nordisk will make the REMS, the Direct Mail letter, the Medication Guide, and professional labeling available via a REMS-specific linkage from the VICTOZA[®] website. The Medication Guide and professional labeling will also be available via hardcopy from Novo Nordisk representatives and through Novo Nordisk's Call Center.

Please see the appended VICTOZA[®] REMS landing page screenshot.

B. Timetable for Submission of Assessments

Novo Nordisk will submit REMS Assessments to FDA at 1 year, 2 years, 3 years, and 7 years from the date of the approval of the initial REMS. The assessments should be submitted by March 24 of each year. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Novo Nordisk will submit each assessment so that it will be received by the FDA on or before the due date .