

Initial REMS approval: 01/2010

Most recent modification: 09/2016

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

Novo Nordisk Inc.

800 Scudders Mill Road, Plainsboro, NJ 08536

Phone: 609-786-4690

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL

The goal of the VICTOZA[®] REMS is to mitigate the potential risk of medullary thyroid carcinoma and the risk of acute pancreatitis (including necrotizing pancreatitis) associated with VICTOZA[®] by:

- Informing healthcare 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 likely to prescribe VICTOZA[®]. The communication plan will include:

1. REMS Letters

Novo Nordisk will send a REMS Letter for Healthcare Providers and REMS Letter for Professional Societies within 60 days of approval of the 07/01/15 REMS modification and again 1 year after approval of the REMS modification (07/01/16). The REMS Letters will address the potential risk of medullary thyroid tumors and the risk of acute pancreatitis. REMS Letters will be distributed by US mail.

On a quarterly basis, any newly identified healthcare providers who prescribed or are likely to prescribe VICTOZA[®] will be mailed the REMS Letter, Prescribing Information (PI) and the REMS Factsheet for the first 18 months after approval of the REMS modification (07/01/2015). In addition, Novo Nordisk will make the REMS Letter for Healthcare Providers available through Novo Nordisk's Medical Information Department and from Novo Nordisk sales and/or medical representatives upon request for one year after approval of the REMS modification (07/01/2015).

a. REMS Letter for Healthcare Providers

The intended audience for the REMS Letter for Healthcare Providers will be physicians, nurse practitioners, and physicians' assistants in the specialties of internal medicine and family practice.

b. REMS Letter for Professional Societies

Novo Nordisk will send the REMS Letter for Professional Societies to the leadership of the following professional societies and organizations requesting the letter be provided to their membership:

- American College of Physicians
- American Academy of Family Physicians
- American College of Osteopathic Family Physicians
- American Academy of Nurse Practitioners
- American Association of Diabetes Educators
- American Academy of Physician Assistants

2. REMS Factsheet

A REMS Factsheet will be made available for healthcare providers and distributed through Novo Nordisk sales representatives during a follow-up visit with healthcare providers detailed/visited for the first 18 months after approval of the REMS modification (07/01/2015).

3. REMS Slides

The REMS Slides will provide information about the potential risk of medullary thyroid carcinoma and the risk of acute pancreatitis (including necrotizing pancreatitis) associated with VICTOZA[®]. The REMS Slides will be part of a slide deck used at Novo Nordisk sponsored training/programs for the first 18 months after approval of the REMS modification (07/01/2015).

4. Dissemination of REMS information at scientific meetings

VICTOZA[®] REMS Factsheet will be prominently displayed and disseminated together with responses to medical information requests at all scientific meetings where Novo Nordisk Medical Information has a presence (e.g., booth) for the first 18 months after approval of the REMS modification (07/01/2015).

5. REMS Website

The VICTOZA[®] REMS website (www.victozapro.com/REMS) will continue for 7 years from the initial approval of the REMS (01/25/2010). The VICTOZA[®] REMS website will include downloadable versions of the PI, REMS Letters, REMS Factsheet, and the REMS Slides. The VICTOZA[®] website for healthcare professionals (www.victozapro.com) and for consumers (www.victoza.com) will include a prominent REMS-specific link to the VICTOZA[®] REMS

website. All website information will be updated within 60 calendar days post approval of this modification.

The following are part of the REMS and are appended:

- The REMS Letter for Healthcare Providers (print version)
- The REMS Letter for Professional Societies (print version)
- The REMS Factsheet
- REMS Slides
- The VICTOZA[®] REMS Website (landing page)

B. Timetable for Submission of Assessments

Novo Nordisk will submit REMS Assessments to FDA at 1 year, 2 years, 3 years, 6 years and 7 years from the date of the approval of the initial REMS (01/25/2010). 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 calendar 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.