

**Initial REMS approval: 12/2014**

**Most recent modification: 2/2016**

**NDA 206321**

**SAXENDA<sup>®</sup> (liraglutide [rDNA origin] injection)**

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**RISK EVALUATION AND MITIGATION STRATEGY (REMS)**

**I. GOAL**

The goal of the SAXENDA<sup>®</sup> REMS is to mitigate the potential risk of medullary thyroid carcinoma and the risk of acute pancreatitis (including necrotizing pancreatitis) associated with SAXENDA<sup>®</sup> by:

- Informing healthcare providers about the potential risk of medullary thyroid carcinoma associated with SAXENDA<sup>®</sup>
- Informing healthcare providers about the risk of acute pancreatitis (including necrotizing pancreatitis) associated with SAXENDA<sup>®</sup>

**II. REMS ELEMENTS**

**A. Communication Plan**

Novo Nordisk will implement the following communication plan to healthcare providers likely to prescribe SAXENDA<sup>®</sup>. The communication plan will include:

**1. REMS Letters**

Novo Nordisk will send a REMS Letter for Healthcare Providers and a REMS Letter for Professional Societies within 30 calendar days of the REMS modification approval (February 2016). The REMS Letters will address the potential risk of medullary thyroid carcinoma and the risk of acute pancreatitis. REMS Letters will be distributed by US mail. If a REMS Letter is undeliverable, Novo Nordisk will use available resources to obtain updated address information

and send a second letter via US mail within 45 calendar days. If the proper address cannot be obtained, the communication will not be sent again. A copy of the Prescribing Information (PI), Medication Guide, and REMS Factsheet will accompany the REMS Letters.

a) REMS Letter for Healthcare Providers.

The intended audience for the REMS Letter for Healthcare Providers is healthcare providers who are likely to prescribe SAXENDA<sup>®</sup> and includes general practitioners, family practitioners, internists, gynecologists, endocrinologists, gastroenterologists, cardiologists, nurse practitioners and physician assistants.

The REMS Letter for Healthcare Providers will also be available via a link from the SAXENDA<sup>®</sup> REMS website, through Novo Nordisk Customer Care center and from Novo Nordisk sales and medical representatives for the duration of the REMS.

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 or its content be provided to their membership:

- American Academy of Family Physicians (AAFP)
- American Academy of Nurse Practitioners (AANP)
- American Academy of Physicians Assistants (AAPA)
- American Association of Clinical Endocrinologists (AAACE)
- American Association of Diabetic Educators (AADE)
- American Board of Physician Nutrition Specialists (ABPNS)
- American College of Cardiology (ACC)
- American College of Obstetricians and Gynecologists (ACOG)
- American College of Physicians (ACP)
- American College of Preventive Medicine (ACPM)
- American Diabetes Association (ADA)
- American Gastroenterological Association (AGA)
- American Heart Association (AHA)
- American Medical Association (AMA)

- American Osteopathic Association (AOA)
- American Pharmacists Association (APhA)
- American Society for Metabolic and Bariatric Surgery (ASMBS)
- American Society for Preventive Cardiology (ASPC)
- American Society of Bariatric Physicians (ASBP)
- The Endocrine Society (ENDO)
- The Obesity Society (TOS)

## **2) REMS Factsheet**

A REMS Factsheet will be made available to healthcare providers and distributed through Novo Nordisk SAXENDA<sup>®</sup> field based sales or medical representatives during the initial healthcare provider discussion within the first 18 months after the initial approval of this REMS. Novo Nordisk SAXENDA<sup>®</sup> field based sales or medical representatives will orally review each risk message contained in the Factsheet.

## **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 SAXENDA<sup>®</sup>. The REMS Slides will be available at the SAXENDA<sup>®</sup> REMS website within 30 calendar days of the REMS modification approval (February 2016) and will be part of a slide deck used at Novo Nordisk sponsored speaker training and promotional programs beginning 2015. The REMS Slides will be posted on the SAXENDA<sup>®</sup> REMS website for the duration of the REMS.

## **4) Dissemination of REMS information at scientific meetings**

The SAXENDA<sup>®</sup> 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 initial the duration of the REMS.

## 5) REMS Website

The SAXENDA<sup>®</sup> REMS website ([www.SAXENDA.com/REMS](http://www.SAXENDA.com/REMS)) will continue for the duration of the REMS. The REMS website will include the option to print versions of the PI, REMS Letter for Healthcare Providers, REMS Factsheet and the REMS slides. The SAXENDA website for healthcare professionals ([www.SAXENDAPRO.com](http://www.SAXENDAPRO.com)) and the consumer websites ([www.Saxenda.com](http://www.Saxenda.com) and [www.SaxendaCare.com](http://www.SaxendaCare.com)) will include a prominent REMS-specific link to SAXENDA<sup>®</sup> REMS website.

The following are part of the REMS and are appended:

- The REMS Letter for Healthcare Providers
- The REMS Letter for Professional Societies
- The REMS Factsheet
- REMS Slides
- The SAXENDA<sup>®</sup> REMS Website (landing page)

### **B. Timetable for Submission of Assessments**

Novo Nordisk will submit REMS Assessments to FDA at 18 months, 3 years, and 7 years from the date of the approval of the initial REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment will 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.