Saxenda®  
liraglutide injection 3 mg

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use SAXENDA® safely and effectively. See full prescribing information for SAXENDA®.

SAXENDA® (liraglutide) injection, for subcutaneous use

Initial U.S. Approval: 2010

WARNING: RISK OF THYROID C-CELL TUMORS
See full prescribing information for complete boxed warning.

• Liraglutide causes thyroid C-cell tumors at clinically relevant exposures in both genders of rats and mice. It is unknown whether Saxenda® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as the human relevance of liraglutide-induced rodent thyroid C-cell tumors has not been determined (5.1).
• Saxenda® is contraindicated in patients with a personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk of MTC and the symptoms of thyroid tumors (4, 5.1, 13.1).

—-RECENT MAJOR CHANGES ———
Indications and Usage, Limitations of Use (1)…………..10/2018

—-INDICATIONS AND USAGE ———

Saxenda® is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of:
• 30 kg/m² or greater (obese) (1) or
• 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g. hypertension, type 2 diabetes mellitus, or dyslipidemia) (1).

Limitations of Use:
• Saxenda® is not indicated for the treatment of type 2 diabetes (1).
• Saxenda® should not be used in combination with any other GLP-1 receptor agonist (1).
• Saxenda® should not be used with insulin (1, 5.4).

• The safety and efficacy of coadministration with other products for weight loss have not been established (1).

—- DOSAGE AND ADMINISTRATION ———

• Recommended dose of Saxenda® is 3 mg daily. Administer at any time of day, without regard to the timing of meals (2).
• Initiate at 0.6 mg per day for one week. In weekly intervals, increase the dose until a dose of 3 mg is reached (2).
• Inject subcutaneously in the abdomen, thigh or upper arm (2).
• The injection site and timing can be changed without dose adjustment (2).

• Injection, pre-filled, multi-dose pen that delivers doses of 0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg or 3 mg (6 mg/mL, 3 mL) (3).

—- CONTRAINDICATIONS ———

• Personal or family history of medullary thyroid carcinoma or Multiple Endocrine Neoplasia syndrome type 2 (4, 5.1).
• Hypersensitivity to liraglutide or any product components (4, 5.7).
• Pregnancy (4, 8.1).

—-WARNINGS AND PRECAUTIONS ———

• Thyroid C-cell Tumors: See Boxed Warning (5.1).
• Acute Pancreatitis: Discontinue promptly if pancreatitis is suspected. Do not restart if pancreatitis is confirmed (5.2).
• Acute Gallbladder Disease: If cholelithiasis or cholecystitis are suspected, gallbladder studies are indicated (5.3).
• Serious Hypoglycemia: Can occur when Saxenda® is used with an insulin secretagogue (e.g. a sulfonylurea). Consider lowering the dose of anti-diabetic drugs to reduce the risk of hypoglycemia (2, 5.4).
• Heart Rate Increase: Monitor heart rate at regular intervals (5.5).
• Renal Impairment: Has been reported postmarketing, usually in association with nausea, vomiting, diarrhea, or dehydration which may sometimes require hemodialysis. Use caution when initiating or escalating doses of Saxenda® in patients with renal impairment (5.6).
• Hypersensitivity Reactions: Postmarketing reports of serious hypersensitivity reactions (e.g., anaphylactic reactions and angioedema). Discontinue Saxenda® and other suspect medications and promptly seek medical advice (5.7).
• Suicidal Behavior and Ideation: Monitor for depression or suicidal thoughts. Discontinue Saxenda® if symptoms develop (5.8).

—-ADVERSE REACTIONS ———

• Most common adverse reactions, reported in greater than or equal to 5% are: nausea, hypoglycemia, diarrhea, constipation, vomiting, headache, decreased appetite, dyspepsia, fatigue, dizziness, abdominal pain, and increased lipase (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact Novo Nordisk Inc. at 1-844-363-4448 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

—-DRUG INTERACTIONS ———

• Saxenda® delays gastric emptying. May impact absorption of concomitantly administered oral medications. Use with caution (7).

—- USE IN SPECIFIC POPULATIONS ———

• Pediatric Use: Safety and effectiveness not established and use not recommended (8.4).

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 10/2018
Saxenda® (liraglutide) injection

FULL PRESCRIBING INFORMATION

WARNING: RISK OF THYROID C-CELL TUMORS

• Liraglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures in both genders of rats and mice. It is unknown whether Saxenda® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as the human relevance of liraglutide-induced rodent thyroid C-cell tumors has not been determined [see Warnings and Precautions (5.1) and Nonclinical Toxicology (13.1)].

• Saxenda® is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk of MTC with use of Saxenda® and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Saxenda® [see Contraindications (4), Warnings and Precautions (5.1)].

INDICATIONS AND USAGE

Saxenda® is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of:
- ≥ 30 kg/m² or greater (obese), or
- ≥ 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia).

DOSAGE AND ADMINISTRATION

The recommended dosage of Saxenda® is 3 mg daily. The dose escalation schedule in Table 1 should be used to reduce the likelihood of gastrointestinal symptoms. If patients do not tolerate an increased dose during dose escalation, consider delaying dose escalation for approximately one additional week. Saxenda® should be discontinued, however, if a patient cannot tolerate the 3 mg dose, as efficacy has not been established at lower doses (0.6, 1.2, 1.8, and 2.4 mg).

Table 1. Dose Escalation Schedule

<table>
<thead>
<tr>
<th>Week</th>
<th>Daily Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.6 mg</td>
</tr>
<tr>
<td>2</td>
<td>1.2 mg</td>
</tr>
<tr>
<td>3</td>
<td>1.8 mg</td>
</tr>
<tr>
<td>4</td>
<td>2.4 mg</td>
</tr>
<tr>
<td>5 and onward</td>
<td>3 mg</td>
</tr>
</tbody>
</table>

Based on spontaneous postmarketing reports, acute pancreatitis, including persistent severe abdominal pain, sometimes radiating to the back and which may or may not be accompanied by vomiting, has been reported with use of Saxenda®. If symptoms of pancreatitis occur, withholding Saxenda® may be necessary in some cases. If acute pancreatitis is diagnosed, use of Saxenda® should be permanently discontinued. Other gastrointestinal symptoms associated with reinitiation of treatment include: nausea, vomiting, diarrhea, anorexia, constipation, and abdominal pain.

DOSAGE FORMS AND STRENGTHS

Saxenda® is supplied as a pre-filled, multiple-dose pen that delivers doses of 0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg, or 3 mg (6 mg/mL, 3 mL).

CONTRAINDICATIONS

Saxenda® is contraindicated in:
- Patients with a personal or family history of medullary thyroid carcinoma (MTC) or patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2) [see Warnings and Precautions (5.1)].
- Patients with a prior serious hypersensitivity reaction to liraglutide or to any of the product components [see Warnings and Precautions (5.7)].
- Pregnancy [see Use in Specific Populations (8.1)].

WARNINGS AND PRECAUTIONS

5.1 Risk of Thyroid C-Cell Tumors

Liraglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors (adenomas and/or carcinomas) at clinically relevant exposures in both genders of rats and mice [see Nonclinical Toxicology (13.1)]. Malignant thyroid C-cell carcinomas were detected in rats and mice. It is unknown whether Saxenda® will cause thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as the human relevance of liraglutide-induced rodent thyroid C-cell tumors has not been determined.

Cases of MTC in patients treated with liraglutide have been reported in the postmarketing period; the data in these reports are insufficient to establish or exclude a causal relationship between MTC and liraglutide use in humans.

Saxenda® is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2. Counsel patients regarding the potential risk for MTC with the use of Saxenda® and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Saxenda®. Such monitoring may increase the risk of unnecessary procedures, due to low test specificity for serum calcitonin and a high background incidence of thyroid disease. Significantly elevated serum calcitonin may indicate MTC, and patients with MTC usually have calcitonin values greater than 50 pg/mL. If serum calcitonin is measured and found to be elevated, the patient should be further evaluated. Patients with thyroid nodules noted on physical examination or neck imaging should also be further evaluated.

5.2 Acute Pancreatitis

Based on spontaneous postmarketing reports, acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with liraglutide. After initiation of Saxenda®, observe patients carefully for signs and symptoms of pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back and which may or may not be accompanied by vomiting). If pancreatitis is suspected, Saxenda® should promptly be discontinued and appropriate management should be initiated. If pancreatitis is confirmed, Saxenda® should not be restarted.

Table 2. BMI Conversion Chart

<table>
<thead>
<tr>
<th>Weight (lb)</th>
<th>Weight (kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>125</td>
<td>56.8</td>
</tr>
<tr>
<td>130</td>
<td>59.1</td>
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<tr>
<td>135</td>
<td>61.4</td>
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<tr>
<td>140</td>
<td>63.6</td>
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<td>145</td>
<td>65.9</td>
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<tr>
<td>150</td>
<td>68.2</td>
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<td>155</td>
<td>70.5</td>
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<td>160</td>
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<tr>
<td>195</td>
<td>88.6</td>
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<tr>
<td>200</td>
<td>90.9</td>
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<tr>
<td>205</td>
<td>93.2</td>
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<tr>
<td>210</td>
<td>95.5</td>
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<tr>
<td>215</td>
<td>97.7</td>
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<tr>
<td>220</td>
<td>100.0</td>
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<tr>
<td>225</td>
<td>102.3</td>
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</table>

Table 2. BMI Conversion Chart

<table>
<thead>
<tr>
<th>Height (in)</th>
<th>Height (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>58</td>
<td>147.3</td>
</tr>
<tr>
<td>59</td>
<td>149.9</td>
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<tr>
<td>60</td>
<td>152.4</td>
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<tr>
<td>61</td>
<td>154.9</td>
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<tr>
<td>62</td>
<td>157.5</td>
</tr>
<tr>
<td>63</td>
<td>160.0</td>
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<tr>
<td>64</td>
<td>162.6</td>
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<tr>
<td>65</td>
<td>165.1</td>
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<td>66</td>
<td>167.6</td>
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<td>67</td>
<td>170.2</td>
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<td>68</td>
<td>172.7</td>
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<td>69</td>
<td>175.3</td>
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<tr>
<td>70</td>
<td>177.8</td>
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<tr>
<td>71</td>
<td>180.3</td>
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<tr>
<td>72</td>
<td>182.9</td>
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<tr>
<td>73</td>
<td>185.5</td>
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<tr>
<td>74</td>
<td>188.0</td>
</tr>
<tr>
<td>75</td>
<td>190.5</td>
</tr>
<tr>
<td>76</td>
<td>193.0</td>
</tr>
</tbody>
</table>

Height (in) 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76
Height (cm) 150 152.4 154.9 157.5 160.0 162.6 165.1 167.6 170.2 172.7 175.3 177.8 180.3 182.9 185.5 188.0 190.5 193.0

DOSAGE FORMS AND STRENGTHS

Solution for subcutaneous injection, pre-filled, multi-dose pen that delivers doses of 0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg, or 3 mg (6 mg/mL, 3 mL).

CONTRAINDICATIONS

Saxenda® is contraindicated in:
- Patients with a personal or family history of medullary thyroid carcinoma (MTC) or patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2) [see Warnings and Precautions (5.1)].
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- Pregnancy [see Use in Specific Populations (8.1)].

WARNINGS AND PRECAUTIONS

5.1 Risk of Thyroid C-Cell Tumors

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5.2 Acute Pancreatitis

Based on spontaneous postmarketing reports, acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with liraglutide. After initiation of Saxenda®, observe patients carefully for signs and symptoms of pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back and which may or may not be accompanied by vomiting). If pancreatitis is suspected, Saxenda® should promptly be discontinued and appropriate management should be initiated. If pancreatitis is confirmed, Saxenda® should not be restarted.
In Saxenda® clinical trials, acute pancreatitis was confirmed by adjudication in 9 (0.3%) of 3291 Saxenda®-treated patients and 2 (0.1%) of 1843 placebo-treated patients. In addition, there were 2 cases of acute pancreatitis in Saxenda®-treated patients who prematurely withdrew from these clinical trials, occurring 74 and 124 days after the last dose. There were 2 additional cases in Saxenda®-treated patients, 1 during an off-treatment follow-up period within 2 weeks of discontinuing Saxenda® and 1 that occurred in a patient who completed treatment and was managed as an acute pancreatitis case. Liraglutide has been studied in a limited number of patients with a history of pancreatitis. It is unknown if patients with a history of pancreatitis are at higher risk for development of pancreatitis on Saxenda®.

5.3 Acute Gallbladder Disease

In Saxenda® clinical trials, 2.2% of Saxenda®-treated patients reported adverse events of cholelithiasis or cholecystitis, respectively, compared with 0.8% of placebo-treated patients. The incidence of cholelithiasis was 0.8% in Saxenda®-treated patients versus 0.4% in placebo-treated patients. The majority of Saxenda®-treated patients with adverse events of cholecystitis or cholelithiasis required cholecystectomy treatment. Substantial or rapid weight loss can increase the risk of cholelithiasis; however, the incidence of acute gallbladder disease was greater in Saxenda®-treated patients than in placebo-treated patients even after accounting for the degree of weight loss. If cholelithiasis is suspected, gallbladder studies and appropriate clinical follow-up are indicated.

5.4 Risk for Hypoglycemia with Concomitant Use of Anti-Diabetic Therapy

The risk for serious hypoglycemia is increased when Saxenda® is used in combination with insulin secretagogues (for example, sulfonylureas) in patients with type 2 diabetes mellitus. Therefore, patients may require a lower dose of sulfonylurea (or other coadministered anti-diabetic drug) in this setting (see Dosage and Administration (2.2) and Adverse Reactions (6.1)). Saxenda® should not be used in patients taking insulin. Saxenda® can lower blood glucose (see Clinical Pharmacology (12.2)). Monitor blood glucose parameters prior to starting Saxenda® and during Saxenda® treatment in patients with type 2 diabetes. It may need to be adjusted to minimize the risk of hypoglycemia based on glucose monitoring results and risk of hypoglycemia.

5.5 Heart Rate Increase

Mean increases in resting heart rate of 2 to 3 beats per minute (bpm) were observed with routine clinical monitoring in Saxenda®-treated patients compared to placebo in clinical trials. More patients (2.2%) in the Saxenda®-treated group had decreases of 6% or greater in heart rate at the second study visit compared with placebo. In clinical trials involving patients without type 2 diabetes mellitus, 15% with type 2 diabetes, 34% with dyslipidemia, 29% with hypertension, 15% with type 2 diabetes, 34% with dyslipidemia, 29% with hypertension, and 15% of patients taking concomitant insulin. Heart rate should be monitored at regular intervals consistent with usual clinical practice. Patients should inform health care providers of any palpitations or unexplained fatigue. In a clinical pharmacology trial that monitored heart rate continuously for 24 hours, Saxenda® treatment was associated with a heart rate that was 4 to 9 bpm higher than that observed with placebo. Heart rate should be monitored at regular intervals consistent with usual clinical practice. Patients should inform health care providers of any palpitations or unexplained fatigue.

In clinical trials, 9.8% of patients treated with Saxenda® and 4.3% of patients treated with placebo prematurely discontinued treatment as a result of adverse events. The most common adverse reactions leading to discontinuation were nausea (2.3% versus 0.2% for Saxenda®-treated patients and placebo, respectively), vomiting (1.7% versus less than 0.1%), and diarrhea (1.4% versus 0%). Adverse reactions reported in greater than or equal to 2% of Saxenda®-treated patients and more frequently than in placebo-treated patients are shown in Table 3.

Table 3. Adverse Reactions Reported in Greater Than or Equal to 2% of Saxenda®-treated Patients and More Frequently Than with Placebo

<table>
<thead>
<tr>
<th>Reaction</th>
<th>Saxenda® N = 3384 %</th>
<th>Placebo N = 1941 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrointestinal Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td>13.8</td>
<td>39.3</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>9.9</td>
<td>20.9</td>
</tr>
<tr>
<td>Constipation</td>
<td>8.5</td>
<td>19.4</td>
</tr>
<tr>
<td>Vomiting</td>
<td>3.9</td>
<td>15.7</td>
</tr>
<tr>
<td>Dyspepsia</td>
<td>2.7</td>
<td>9.6</td>
</tr>
<tr>
<td>Abdominal Pain</td>
<td>3.1</td>
<td>5.4</td>
</tr>
<tr>
<td>Upper Abdominal Pain</td>
<td>2.7</td>
<td>5.1</td>
</tr>
<tr>
<td>Gastroesophageal Reflux Disease</td>
<td>1.7</td>
<td>4.7</td>
</tr>
<tr>
<td>Abdominal Distension</td>
<td>3.0</td>
<td>4.5</td>
</tr>
<tr>
<td>Eruption</td>
<td>0.2</td>
<td>4.5</td>
</tr>
<tr>
<td>Flatulence</td>
<td>2.5</td>
<td>4.0</td>
</tr>
<tr>
<td>Dry Mouth</td>
<td>1.0</td>
<td>2.3</td>
</tr>
</tbody>
</table>

5.6 Renal Impairment

In patients treated with GLP-1 receptor agonists, including Saxenda®, there have been reports of acute renal failure and worsening of chronic renal failure, sometimes requiring hemodialysis (see Adverse Reactions (6.2)). Some of these events were reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, or diarrhea leading to volume depletion. Some of the reported events occurred in patients receiving one or more medications known to affect renal function or volume status. If renal function has been reversed in many of the reported cases with supportive treatment and discontinuation of potentially causative agents, including liraglutide. Use caution when initiating or escalating doses of Saxenda® in patients with renal impairment (see Use in Special Populations (8.6)).

5.7 Hypersensitivity Reactions

There have been reports of serious hypersensitivity reactions (e.g., anaphylactic reactions and angioedema) in patients treated with liraglutide (see Contraindications (4) and Adverse Reactions (6.3)). If a hypersensitivity reaction occurs, the patient should discontinue Saxenda® and other suspect medications and promptly seek medical advice.

Anaphylaxis and angioedema have been reported with other GLP-1 receptor agonists. Use caution in a patient with a history of anaphylaxis or angioedema with another GLP-1 receptor agonist because it is unknown whether such patients will be predisposed to these reactions with Saxenda®.

5.8 Suicidal Behavior and Ideation

In Saxenda® clinical trials, 9 (0.3%) of 3384 Saxenda®-treated patients and 2 (0.1%) of 1941 of the placebo-treated patients reported suicidal ideation, one of these Saxenda®-treated patients attempted suicide. Patients treated with Saxenda® should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Discontinue Saxenda® in patients who experience suicidal thoughts or behaviors. Avoid Saxenda® in patients with a history of suicidal attempts or active suicidal ideation.

6 ADVERSE REACTIONS

The following serious adverse reactions are described below or elsewhere in the prescribing information:

1. Risk of Thyroid C-Cell Tumors [see Warnings and Precautions (5.1)]

2. Acute Pancreatitis [see Warnings and Precautions (5.2)]

3. Acute Gallbladder Disease [see Warnings and Precautions (5.3)]

4. Risk for Hypoglycemia with Concomitant Use of Anti-Diabetic Therapy [see Warnings and Precautions (5.4)]

5. Heart Rate Increase [see Warnings and Precautions (5.5)]

6. Renal Impairment [see Warnings and Precautions (5.6)]

7. Hypersensitivity Reactions [see Warnings and Precautions (5.7)]

8. Suicidal Behavior and Ideation [see Warnings and Precautions (5.8)]
Lab Abnormalities

Liver Enzymes

Increases in alanine aminotransferase (ALT) greater than or equal to 10 times the upper limit of normal were observed in 5 (0.15%) Saxenda®-treated patients (two of whom had ALT greater than 20 times the upper limit of normal) compared with 1 (0.05%) placebo-treated patient during the Saxenda® clinical trials. Because clinical evaluation to exclude alternative causes of ALT and aspartate aminotransferase (AST) increases was not done in most cases, a causal relationship to Saxenda® is uncertain. Some increases in ALT and AST were associated with other confounding factors (such as gallstones).

Serum Calcitonin

Calcitonin, a biological marker of MTC, was measured throughout the clinical development (5.1). More patients treated with Saxenda® in the clinical trials were observed to have high calcitonin values during treatment, compared with placebo. The proportion of patients with calcitonin greater than or equal to 2 times the upper limit of normal at the end of the trial was 1.2% in Saxenda®-treated patients and 0.6% in placebo-treated patients. Calcitonin values greater than 20 ng/L at the end of the trial occurred in 0.5% of Saxenda®-treated patients and 0.2% of placebo-treated patients; among patients with pre-existing MTC on baseline calcitonin or amylose with Saxenda® is unknown in the absence of other signs and symptoms of parathyroid cancer (see Warnings and Precautions (5.2)).

2.6 Post-Marketing Experience

The following adverse reactions have been reported during post-marketing experience with Saxenda®. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Neoplasms

Medullary thyroid carcinoma (see Warnings and Precautions (5.1)).

Gastrointestinal Disorders

Acute pancreatitis, hypergastrinemia and necrotizing pancreatitis, sometimes resulting in death (see Warnings and Precautions (5.2)).

Metabolism and Nutrition Disorders

Dehydration resulting from nausea, vomiting and diarrhea (see Adverse Reactions (6.1)).

Renal and Urinary Disorders

Increased serum creatinine, acute renal failure or worsening of chronic renal failure (see Warnings and Precautions (5.6)).

General Disorders and Administration Site Conditions

Allergic reactions: rash and pruritus (see Adverse Reactions (6.1)).

Immune System Disorders

Angioedema and anaphylactic reactions (see Warnings and Precautions (5.7)).

Hepatobiliary Disorders

Elevated liver enzymes, hyperbilirubinemia, cholestasis and hepatitis (see Adverse Reactions (6.1)).

7 DRUG INTERACTIONS

7.1 Oral Medications

Saxenda® causes a delay of gastric emptying, and thereby has the potential to impact the absorption of concomitantly administered oral medications. In clinical pharmacology trials, saxenda did not affect the absorption of metformin. Therefore, saxenda is not expected to impact to any clinically relevant degree. Nonetheless, monitor for potential consequences of delayed absorption of oral medications concomitantly administered with saxenda (5.5).

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Saxenda® is contraindicated during pregnancy because weight loss offers no potential benefit to a pregnant woman and may result in fetal harm (see Clinical Considerations). There are no available data with saxenda in pregnant women to inform a drug risk-benefit assessment for major birth defects and miscarriage. Saxenda® should not be used during pregnancy. If a patient wishes to become pregnant, or pregnancy occurs, treatment with saxenda should be discontinued. Animal reproduction studies identified increased adverse embryo-fetal developmental outcomes from exposure during pregnancy.

Liraglutide exposure was associated with early embryonic deaths and an imbalance in some fetal abnormalities in pregnant rats administered liraglutide during organogenesis at doses that approximated clinical exposures at the maximum recommended human dose (MRHD) of 3 mg/day, or equivalent. Rats administered saxenda during organogenesis, decreased fetal weight and an increased incidence of major fetal abnormalities were seen at exposures below the human exposures at the MRHD (see Animal Data). The estimated background risk of major birth defects and miscarriage in humans is not known. In general, animal data cannot be directly compared to clinical data due to differences in test conditions, species sensitivity and/or dose. Nonetheless, monitor for potential consequences of delayed absorption of orally administered medications concomitantly administered with saxenda (5.5).

8.2 Lactation

Risk Summary

There are no data on the presence of saxenda in human milk, the effects on the breastfed infant, or effects on milk production. Therefore, it is not known whether breastfed infants may be exposed to saxenda through human milk. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for saxenda® and any potential adverse effects on the breastfed infant from saxenda® or from the underlying maternal condition.
8.4 Pediatric Use
Safety and effectiveness of Saxenda® have not been established in pediatric patients. Saxenda® is not recommended for use in pediatric patients.

8.5 Geriatric Use
In the Saxenda® clinical trials, 232 (6.9%) of the Saxenda®-treated patients were 65 years of age and over, and 17 (0.5%) of the Saxenda®-treated patients were 75 years of age and over. No overall differences in safety or effectiveness were observed between these patients and younger patients. However, greater sensitivity of some older individuals cannot be ruled out.

8.6 Renal Impairment
There is limited experience with Saxenda® in patients with mild, moderate, and severe renal impairment, including end-stage renal disease. However, there have been postmarketing reports of acute renal failure and worsening of chronic renal failure with liraglutide, which may sometimes require hemodialysis (see Warnings and Precautions (5.6) and Adverse Reactions (6.2)). Saxenda® should be used with caution in this patient population (see Clinical Pharmacology (12.3)).

8.7 Hepatic Impairment
There is limited experience in patients with mild, moderate, or severe hepatic impairment. Therefore, Saxenda® should be used with caution in this patient population (see Clinical Pharmacology (12.3)).

8.8 Gastroesophageal Reflux Disease
Saxenda® slows gastric emptying. Saxenda® has not been studied in patients with pre-existing gastroesophageal reflux disease.

10 OVERDOSAGE
Overdoses have been reported in clinical trials and post-marketing use of liraglutide. Effects have included severe nausuea and severe vomiting. In the event of overdose, appropriate supportive treatment should be initiated according to the patient’s clinical signs and symptoms.

11 DESCRIPTION
Saxenda® contains liraglutide, an analog of human GLP-1 and acts as a GLP-1 receptor agonist. The peptide precursor of liraglutide, produced by a process that includes expression of recombinant DNA in Saccharomyces cerevisiae, has been engineered to be 97% homologous to native human GLP-1 by substituting arginine for lysine at position 34. Liraglutide is made by attaching a C-16 fatty acid (palmitic acid) with a glucamic acid spacer on the remaining lysine residue at position 26 of the peptide precursor. The molecular formula of liraglutide is C₁₁₂H₁₇₀N₉₂O₄₅S₄ and the molecular weight is 3751.2 Dalton. The structural formula (1) is:

\[
\text{C₁₁₂H₁₇₀N₉₂O₄₅S₄} \quad \text{(mol. wt. 3751.2 Da)}
\]

Figure 1. Structural Formula of Liraglutide

Saxenda® is a clear, colorless solution. Each 1 mL of Saxenda® solution contains 6 mg of liraglutide and the following inactive ingredients: disodium phosphate dihydrate, 1.42 mg; propylene glycol, 14 mg; methyl alcohol, 5.6 mg; and water for injection. Each pre-filled pen contains a 3 mL solution of Saxenda® equivalent to 18 mg liraglutide (free-base, anhydrous).

12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
Liraglutide is an acylated human glucagon-like peptide-1 (GLP-1) receptor agonist with 97% amino acid sequence homology to endogenous human GLP-1 (17-37). Like endogenous GLP-1, liraglutide binds to and activates the GLP-1 receptor, a cell surface receptor coupled to adenyl cyclase activation through the stimulatory G-protein, Gs. Endogenous GLP-1 has a half-life of 1-2 minutes in humans, with 98% of the GLP-1 receptor-mediated actions related to cytochrome P450 (CYP) and plasma protein binding, and stability against metabolic degradation by DPP-4 and NEP.

12.2 Pharmacodynamics
Liraglutide lowers body weight through decreased calorie intake. Liraglutide also decreases post-prandial glucose excursions and reduces glucagon secretion in a glucose-dependent manner. These effects can lead to a reduction of blood glucose. Cardiac Electrophysiology (QTc) in healthy volunteers

The effect of liraglutide on cardiac repolarization was tested in a QTc study. Liraglutide at steady-state concentrations after daily doses of 0.6 mg and 1.8 mg did not produce QTc prolongation. The maximum liraglutide plasma concentration (Cmax) in overweight and obese subjects treated with liraglutide 3 mg is similar to the Cmax observed in the liraglutide QTc study in healthy volunteers.

12.3 Pharmacokinetics
Administration of a single subcutaneous dose of liraglutide at steady-state concentrations of liraglutide are achieved at 11 hours post dosing. The average liraglutide steady state concentration (AUC(0-∞)) reached approximately 116 ng/mL in obese (BMI 30-40 kg/m²) subjects following administration of Saxenda®. Liraglutide exposure increased proportionally in the dose range of 0.6 mg to 3 mg. The intra-subject coefficient of variation for liraglutide AUC was 11% following single dose administration. Liraglutide exposures were considered similar among three subcutaneous injection sites (upper arm, abdomen, and thigh). Absolute bioavailability of liraglutide following subcutaneous administration is approximately 55%.

Distribution - The mean apparent volume of distribution after subcutaneous administration of liraglutide 3 mg is 20-25 L (for a person weighing approximately 100 kg). The mean volume of distribution for liraglutide is 15-25 L without a specific organ as a major route of elimination.

Elimination - Following a [3H]-liraglutide dose, intact liraglutide was not detected in urine or feces. Only a minor part of the administered dose was excreted in urine or feces (6% and 5%, respectively).

The major route of liraglutide elimination is through the liver. The extent of liraglutide’s metabolism by hepatic enzymes and systemic first-pass effects are: 50-90% in obese patients and 50-60% for subjects with normal body weight. The Cmax of liraglutide is not altered by administration of meal.

Specific Populations
- Elderly - No dosage adjustment is required based on age.

Race and Ethnicity - Race and ethnicity had no effect on the pharmacokinetics of liraglutide based on the results of population pharmacokinetic analyses that included over 2000 overweight and obese patients of Caucasian, Black, Asian and Hispanic/Non-Hispanic groups.

Body Weight - Body weight significantly affects the pharmacokinetics of liraglutide based on results of population pharmacokinetic analyses conducted in patients with body weight range of 60-234 kg. The exposure of liraglutide decreases as baseline body weight decreases.

13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
A 104-week carcinogenicity study was conducted in male and female CD-1 mice at doses of 0.03, 0.2, 1, and 3 mg/kg/day liraglutide administered by bolus subcutaneous injection yielding systemic exposures 0.2-, 2-, and 10-fold greater than exposure in obese humans, respectively, at the maximum recommended human dose (MRHD) of 3 mg/day based on plasma AUC comparison. A dose-related increase in benign thyroid C-cell adenomas was seen in the 1 and the 3 mg/kg/day groups with incidences of 13% and 19% in males and 6% and 20% in females, respectively. C-cell adenomas did not occur in control groups or 0.03 and 0.2 mg/kg/day groups. Treatment-related malignant C-cell carcinomas were not observed in males in the 3 mg/kg/day group. Thyroid C-cell tumors are rare findings during carcinogenicity testing in mice. A treatment-related increase in fibrosarcomas was seen in the dorsal skin and subcutis, the body surface used for drug injection, in males in the 3 mg/kg/day group. These fibrosarcomas were attributed to the method of drug administration (bolus injection). The incidence of fibrosarcoma in the high dose group was 10-100-fold higher than that observed in wild-type mice. No fibrosarcomas were seen in females in this dose group. In the high-dose group, fibrosarcomas were significantly increased following subcutaneous injection of drug. No fibrosarcomas were observed in lower dose groups. No compound-related treatment-related increases in forestomach, urinary tract, testis, or ovary tumors were observed. Liraglutide at doses of up to 4317 mg/kg/day did not increase the incidence of aneuploidy in spermatogonia of rats in vivo. No spontaneous mutations were observed in liraglutide-treated male and female CD-1 mice or Sprague Dawley rats at doses of 0.05, 0.25 and 0.75 mg/kg/day liraglutide administered by bolus subcutaneous injection with exposures 0.5-, 2- and 7-times the exposure in obese humans, respectively, resulting from the MRHD based on plasma AUC.
AUC comparison. A treatment-related increase in benign thyroid C-cell adenomas was seen in males in 0.25 and 0.75 mg/kg/day liraglutide groups with incidences of 12%, 16%, 42%, and 46% and in all female liraglutide-treated groups with incidences of 10%, 27%, 33%, and 37% for 0.25, 0.75 mg/kg/day groups, respectively. A treatment-related increase in malignant thyroid C-cell carcinomas was observed in all male liraglutide-treated groups with incidences of 2%, 8%, 6%, and 14% and in females at 0.25 mg/kg/day with incidences of 0%, 0.7%, 0.4%, and 6% in 0 (control), 0.075, 0.25, and 0.75 mg/kg/day groups, respectively. Thyroid C-cell carcinomas are rare findings during carcinogenicity testing in rats. Studies in mice demonstrated that liraglutide-induced C-cell proliferation was dependent on the GLP-1 receptor and that liraglutide did not cause activation of the RARE rearranged during transfection (RET) proto-oncogene in thyroid C-cells.

Human relevance of thyroid C-cell tumors in mice and rats is unknown and has not been determined by clinical studies or nonclinical studies [see Boxed Warning and Warnings and Precautions (5.1)].

Liraglutide was negative with and without metabolic activation in the Ames test for mutagenicity and in a human peripheral blood lymphocyte chromosome aberration test for clastogenicity.

Liraglutide was negative in repeat-dose in vivo micronucleus tests in rats. In rat fertility studies using subcutaneous doses of 0.1, 0.25 and 1 mg/kg/day liraglutide, males were treated for 4 weeks prior to and throughout mating and females were treated 2 weeks prior to and throughout mating until gestation day 17. No direct adverse effects on male fertility were observed at doses up to 1 mg/kg/day, a high dose yielding an estimated systemic exposure 11-times the exposure in obese humans at the MRHD, based on plasma AUC comparison. In female rats, an increase in early embryonic deaths occurred at 1 mg/kg/day. Reduced body weight gain and food consumption were observed in females at the 1 mg/kg/day dose.

14 CLINICAL STUDIES

The safety and efficacy of Saxenda® for chronic weight management in conjunction with reduced caloric intake and increased physical activity were studied in three 56-week, randomized, double-blind, placebo-controlled trials. In all studies, Saxenda® was titrated to 3 mg daily during a 4-week period. All patients received instruction for a reduced calorie diet (approximately 500 kcal/day deficit) and exercise counseling (recommended increase in physical activity of minimum 150 mins/week) that began with the first dose of study medication or placebo and continued throughout the trial. Study 1 enrolled 3731 patients with obesity (BMI) greater than or equal to 30 kg/m² or with diabetes and at least one weight-related comorbid condition such as treated or untreated dyslipidemia or hypertension; patients with type 2 diabetes mellitus were excluded. Patients were randomized in a 2:1 ratio to receive either Saxenda® or placebo. Patients were stratified based on the presence or absence of abnormal glucose measurements at randomization. All patients were treated for up to 56 weeks. The cumulative frequency distributions of change in body weight from baseline to week 56 are shown in Figure 2 for Studies 1 and 2. One way to interpret this figure is to select a change in body weight of interest on the horizontal axis and note the corresponding proportions of patients (vertical axis) in each treatment group who achieved at least that degree of weight loss. For example, note that the vertical line resulting from -10% in Study 1 intersects the Saxenda® and placebo curves at approximately 34% and 15%, respectively, which correspond to the values shown in Table 4.

The cumulative frequency distributions of change in body weight from baseline to week 56 are shown in Figure 2 for Studies 1 and 2. One way to interpret this figure is to select a change in body weight of interest on the horizontal axis and note the corresponding proportions of patients (vertical axis) in each treatment group who achieved at least that degree of weight loss. For example, note that the vertical line resulting from -10% in Study 1 intersects the Saxenda® and placebo curves at approximately 34% and 15%, respectively, which correspond to the values shown in Table 4.

Table 4. Changes in Weight at Week 56 for Studies 1, 2, and 3

<table>
<thead>
<tr>
<th>Weight</th>
<th>Saxenda® N=2487</th>
<th>Placebo N=1244</th>
<th>Saxenda® N=423</th>
<th>Placebo N=212</th>
<th>Saxenda® N=212</th>
<th>Placebo N=210</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline mean (SD) (kg)</td>
<td>106.2 (21.2)</td>
<td>106.2 (21.7)</td>
<td>105.7 (21.9)</td>
<td>106.5 (21.3)</td>
<td>100.4 (20.8)</td>
<td>98.7 (21.2)</td>
</tr>
<tr>
<td>Percent change from baseline (LSMean)</td>
<td>-7.4</td>
<td>-3.0</td>
<td>-5.4</td>
<td>-1.7</td>
<td>-4.9</td>
<td>0.3</td>
</tr>
<tr>
<td>Difference from placebo (LSMean) (95% CI)</td>
<td>-4.5* (-5.2; -3.8)</td>
<td>-3.7* (-4.7; -2.7)</td>
<td>-6.2* (-7.8; -4.6)</td>
<td>-6.8* (-8.3; -5.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>% of Patients losing greater than or equal to 5% body weight</td>
<td>62.3%</td>
<td>34.4%</td>
<td>49.0%</td>
<td>16.4%</td>
<td>44.2%</td>
<td>21.7%</td>
</tr>
<tr>
<td>% of Patients losing greater than 10% body weight</td>
<td>33.0%</td>
<td>14.5%</td>
<td>22.4%</td>
<td>5.5%</td>
<td>25.4%</td>
<td>6.9%</td>
</tr>
<tr>
<td>Difference from placebo (LSMean) (95% CI)</td>
<td>18.5* (15.2; 21.7)</td>
<td>16.9* (11.7; 22.1)</td>
<td>18.5* (11.7; 25.3)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SD = Standard Deviation; CI = Confidence Interval
*p < 0.0001 compared to placebo. Type 1 error was controlled across the three endpoints.

Includes all randomized subjects who had a baseline body weight measurement. All available body weight data during the 56 week treatment period are included in the analysis. In Studies 1 and 2 missing values for week 56 were handled using multiple imputations analysis. In Study 3 missing values for week 56 were handled using weighted regression analysis.

The time courses of weight loss with Saxenda® and placebo from baseline through week 56 are depicted in Figures 3 and 4.
Oberved values for patients on study drug completing each scheduled visit, and ITT with weighted average (ITT-WA)

Figure 4. Change from baseline (%) in body weight during Study 3

**Effect of Saxenda® on Body Weight in a 160-week Trial (Study 1, Subset of Patients with Abnormal Blood Glucose at Randomization)**

The numbers and percentages of patients known to have lost greater than or equal to 5% body weight at week 56 and/or week 160 in Study 1 (patients with abnormal glucose at randomization only) are summarized in Table 5 for descriptive purposes.

Table 5. Changes in Weight at Week 56 and Week 160 for Study 1 (Subset of Patients with Abnormal Blood Glucose at Randomization)

<table>
<thead>
<tr>
<th></th>
<th>Saxenda® (N = 1505)</th>
<th>Placebo (N = 749)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline mean weight (SD) (kg)</td>
<td>107.5 (21.6)</td>
<td>107.9 (21.8)</td>
</tr>
<tr>
<td>Number (%) of patients known to lose greater than or equal to 5% body weight at week 56</td>
<td>317 (56%)</td>
<td>182 (25%)</td>
</tr>
<tr>
<td>Number (%) of patients known to lose greater than or equal to 5% body weight at week 160</td>
<td>424 (28%)</td>
<td>102 (14%)</td>
</tr>
<tr>
<td>Number (%) of patients known to lose greater than or equal to 5% body weight at both weeks 56 and 160</td>
<td>391 (26%)</td>
<td>74 (10%)</td>
</tr>
<tr>
<td>Number (%) of patients with weight assessment at 160 weeks</td>
<td>747 (50%)</td>
<td>322 (43%)</td>
</tr>
</tbody>
</table>

SD = Standard Deviation

Includes all randomized subjects who had a baseline body weight measurement. All available body weight data at 56 and 160 weeks are included in the analysis.

**Effect of Saxenda® on Anthropometry and Cardiometabolic Parameters in 56-week Trials**

Changes in waist circumference and cardiometabolic parameters with Saxenda® are shown in Table 6 for Study 1 (patients without diabetes mellitus) and Table 7 for Study 2 (patients with type 2 diabetes). Results from Study 3, which also enrolled patients without diabetes mellitus, were similar to Study 1.

Table 6. Mean Changes in Anthropometry and Cardiometabolic Parameters in Study 1 (Patients without Diabetes)

<table>
<thead>
<tr>
<th></th>
<th>Saxenda® (N = 2487)</th>
<th>Placebo (N = 1212)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Waist Circumference (cm)</td>
<td>Change from Baseline (LSMean)</td>
<td>Change from Baseline (LSMean)</td>
</tr>
<tr>
<td>Baseline</td>
<td>115.0</td>
<td>114.5</td>
</tr>
<tr>
<td>Total Cholesterol (mg/dL)*</td>
<td>-3.2</td>
<td>194.4</td>
</tr>
<tr>
<td>LDL Cholesterol (mg/dL)*</td>
<td>3.1</td>
<td>122.3</td>
</tr>
<tr>
<td>HDL Cholesterol (mg/dL)*</td>
<td>2.3</td>
<td>59.9</td>
</tr>
<tr>
<td>Triglycerides (mg/dL)*</td>
<td>125.7</td>
<td>128.3</td>
</tr>
<tr>
<td>Percent Change from Baseline</td>
<td>10.0</td>
<td>11.8</td>
</tr>
</tbody>
</table>

Based on last observation carried forward method while on study drug

1. Least squares mean adjusted for treatment, country, sex, pre-diabetes status at screening, baseline BMI stratum and an interaction between pre-diabetes status at screening and BMI stratum as fixed factors, and the baseline value as covariate.

2. Baseline value is the geometric mean.

3. Values are baseline median, median % change, and the Hodges-Lehmann estimate of the median treatment difference.

Based on last observation carried forward method while on study drug

1. Least squares mean adjusted for treatment, country, sex, background treatment, baseline HbA1c stratum and an interaction between background treatment and HbA1c stratum as fixed factors, and the baseline value as covariate.

2. Baseline value is the geometric mean.

3. Values are baseline median, median % change, and the Hodges-Lehmann estimate of the median treatment difference.

**Cardiovascular Outcomes Trial of Liraglutide 1.8 mg in Patients with Type 2 Diabetes and Cardiovascular Disease**

Liraglutide 1.8 mg (Victozza®) is used in the treatment of type 2 diabetes mellitus in adults. The efficacy of liraglutide at doses below 3 mg/daily has not been established for chronic weight management. The LEADER trial (NCT01179048) randomized 9340 patients with inadequately controlled type 2 diabetes and cardiovascular disease to liraglutide 1.8 mg or placebo in addition to standard of care treatments for type 2 diabetes for a median duration of 5.5 years. Patients either were 50 years of age or older with established, stable cardiovascular, cerebrovascular, peripheral vascular disease, chronic renal failure or chronic heart failure (80% of patients), or were 60 years of age or older and had other specified risk factors of vascular disease (20% of patients). The population was 64% male, 78% Caucasian, 10% Asian and 8% Black, 12% of the population was Hispanic or Latino.

In total, 96.8% of the patients completed the trial; vital status was known at the end of the trial for 99.7%. The primary endpoint was the time from randomization to first occurrence of a major adverse cardiovascular event (MACE) defined as: cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke. No increased risk for MACE was observed with liraglutide 1.8 mg. The total number of primary component MACE endpoints was 1302 (608 (13.0%) with liraglutide 1.8 mg and 694 (14.9%) with placebo).

**16 HOW SUPPLIED/STORAGE AND HANDLING**

**16.1 How Supplied**

Saxenda® is available in the following package sizes containing disposable, pre-filled, multi-dose pens. Each individual pen delivers doses of 0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg or 3 mg (6 mg/mL, 3 mL).

3 x Saxenda® pen    NDC 0169-2800-13
5 x Saxenda® pen    NDC 0169-2800-15

Each Saxenda® pen is for use by a single patient. A Saxenda® pen should never be shared between patients, even if the needle is changed.

**16.2 Recommended Storage**

Prior to first use, Saxenda® should be stored in a refrigerator between 36°F to 46°F (2°C to 8°C) (Table 8). Do not store in the freezer or directly adjacent to the refrigerator cooling element. Do not freeze Saxenda® and do not use Saxenda® if it has been frozen. After initial use of the Saxenda® pen, the pen can be stored for 30 days at controlled room temperature (59°F to 86°F; 15°C to 30°C) or in a refrigerator (30°F to 46°F; 2°C to 8°C). Keep the pen cap on when not in use. Saxenda® should be protected from excessive heat and sunlight. Always remove and safely discard the needle after each injection and store the Saxenda® pen without an injection needle attached. This will reduce the potential for contamination, infection, and leakage while also ensuring dosing accuracy.

Table 8. Recommended Storage Conditions for Saxenda®

<table>
<thead>
<tr>
<th>Prior to first use</th>
<th>After first use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refrigerated</td>
<td>Room Temperature</td>
</tr>
<tr>
<td>36°F to 46°F</td>
<td>59°F to 86°F</td>
</tr>
<tr>
<td>(2°C to 8°C)</td>
<td>(15°C to 30°C)</td>
</tr>
</tbody>
</table>

Until expiration date

30 days

**17 PATIENT COUNSELING INFORMATION**

**FDA-Approved Medication Guide**

Advises the patient to read the FDA-approved patient labeling (Medication Guide and Instructions for Use).

**Instructions**

Advises patients to take Saxenda® exactly as prescribed. Instruct patients to follow the dose escalation schedule and to not take more than the recommended dose.

Instruct patients to discontinue Saxenda® if they have not achieved 4% weight loss by 16 weeks of treatment.

**Risk of Thyroid C-cell Tumors**

Inform patients that liraglutide causes benign and malignant thyroid C-cell tumors in mice and rats and that the human relevance of this finding has not been determined. Counsel patients to report symptoms of thyroid tumors (e.g., a lump in the neck, hoarseness, dysphagia or dyspepsia) to their health care provider (see Boxed Warning and Warnings and Precautions (5.1)).

**Acute Pancreatitis**

Inform patients of the potential risk for acute pancreatitis. Explain that persistent severe abdominal pain that may radiate to the back which may or may not be accompanied by vomiting is the hallmark symptom of acute pancreatitis. Instruct patients to discontinue Saxenda® promptly and contact their health care provider if persistent severe abdominal pain occurs.

**Acute Gallbladder Disease**

Inform patients of the risk of acute gallbladder disease. Advise patients that substantial or rapid weight loss can increase the risk of gallbladder disease, but that gallbladder disease may also occur in

Based on last observation carried forward method while on study drug

1. Least squares mean adjusted for treatment, country, sex, background treatment, baseline HbA1c stratum and an interaction between background treatment and HbA1c stratum as fixed factors, and the baseline value as covariate.

2. Baseline value is the geometric mean.

3. Values are baseline median, median % change, and the Hodges-Lehmann estimate of the median treatment difference.
the absence of substantial or rapid weight loss. Instruct patients to contact their healthcare provider for appropriate clinical follow-up if gallbladder disease is suspected.

**Hypoglycemia in Patients with Type 2 Diabetes Mellitus on Anti-Diabetic Therapy**

Educate patients on the signs and symptoms of hypoglycemia. Advise patients with type 2 diabetes mellitus on glycemic lowering therapy to report signs and/or symptoms of hypoglycemia to their healthcare provider.

**Heart Rate Increase**

Inform patients to report symptoms of sustained periods of heart pounding or racing while at rest to their healthcare provider. Discontinue Saxenda® in patients who experience a sustained increase in resting heart rate.

**Dehydration and Renal Impairment**

Advise patients of the risk of dehydration due to gastrointestinal adverse reactions and to take precautions to avoid fluid depletion. Inform patients of the potential risk for worsening renal function, which in some cases may require dialysis.

**Hypersensitivity Reactions**

Inform patients that serious hypersensitivity reactions have been reported during postmarketing use of Saxenda®. Advise patients on the symptoms of hypersensitivity reactions and instruct them to stop taking Saxenda® and seek medical advice promptly if such symptoms occur (See Warnings and Precautions (5.7)).

**Suicidal Behavior and Ideation**

Advise patients to report emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Inform patients that if they experience suicidal thoughts or behaviors, they should stop taking Saxenda®.

**Jaundice and Hepatitis**

Inform patients that jaundice and hepatitis have been reported during postmarketing use of liraglutide. Instruct patients to contact their healthcare provider if they develop jaundice.

**Never Share a Saxenda® Pen Between Patients**

Inform patients that they should never share a Saxenda® pen with another person, even if the needle is changed. Sharing of the pen between patients may pose a risk of transmission of infection.
Saxenda® (liraglutide) injection solution for subcutaneous use

What is the most important information I should know about Saxenda®?

Serious side effects may happen in people who take Saxenda®, including:

Possible thyroid tumors, including cancer. Tell your healthcare provider if you get a lump or swelling in your neck, hoarseness, trouble swallowing, or shortness of breath. These may be symptoms of thyroid cancer. In studies with rats and mice, Saxenda® and medicines that work like Saxenda® caused thyroid tumors, including thyroid cancer. It is not known if Saxenda® will cause thyroid tumors or a type of thyroid cancer called medullary thyroid carcinoma (MTC) in people.

Do not use Saxenda® if you or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC), or if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

What is Saxenda®?

Saxenda® is an injectable prescription medicine that may help some obese or overweight adults who also have weight related medical problems lose weight and keep the weight off.

- Saxenda® should be used with a reduced calorie diet and increased physical activity.
- Saxenda® is not for the treatment of type 2 diabetes mellitus.
- Saxenda® and Victoza® have the same active ingredient, liraglutide.
- Saxenda® and Victoza® should not be used together.
- Saxenda® should not be used with other GLP-1 receptor agonist medicines.
- Saxenda® and insulin should not be used together.
- It is not known if Saxenda® is safe and effective when taken with other prescription, over-the-counter, or herbal weight loss products.
- It is not known if Saxenda® changes your risk of heart problems or stroke or of death due to heart problems or stroke.
- It is not known if Saxenda® can be used safely in people who have had pancreatitis.
- It is not known if Saxenda® is safe and effective in children under 18 years of age. Saxenda® is not recommended for use in children.

Who should not use Saxenda®?

Do not use Saxenda® if:

- you or any of your family have a history of medullary thyroid carcinoma.
- you have Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). This is a disease where people have tumors in more than one gland in their body.
- you are allergic to liraglutide or any of the ingredients in Saxenda®. See the end of this Medication Guide for a complete list of ingredients in Saxenda®.
- Symptoms of a serious allergic reaction may include:
  - swelling of your face, lips, tongue, or throat
  - fainting or feeling dizzy
  - very rapid heartbeat
- problems breathing or swallowing
- severe rash or itching
- you are allergic to liraglutide or any of the ingredients in Saxenda®. See the end of this Medication Guide for a list of ingredients in Saxenda®.

Talk with your healthcare provider if you are not sure if you have any of these conditions.
- are pregnant or planning to become pregnant. Saxenda® may harm your unborn baby.

Before taking Saxenda®, tell your healthcare provider about all of your medical conditions, including if you:

- have any of the conditions listed in the section “What is the most important information I should know about Saxenda®?”
- are taking certain medications called GLP-1 receptor agonists.
- are allergic to liraglutide or any of the other ingredients in Saxenda®. See the end of this Medication Guide for a list of ingredients in Saxenda®.
- have severe problems with your stomach, such as slowed emptying of your stomach (gastroparesis) or problems with digesting food.
- or have had problems with your pancreas, kidneys or liver.
- have or have had depression or suicidal thoughts.
- are pregnant or plan to become pregnant. Saxenda® may harm your unborn baby. Tell your healthcare provider if you become pregnant while taking Saxenda®. If you are pregnant you should stop using Saxenda®.
- are breastfeeding or plan to breastfeed. It is not known if Saxenda® passes into your breast milk. You and your healthcare provider should decide if you will take Saxenda® or breastfeed. You should not do both without talking with your healthcare provider first.

Tell your healthcare provider about all the medicines you take including prescription and over-the-counter medicines, vitamins, and herbal supplements. Saxenda® slows stomach emptying and can affect medicines that need to pass through the stomach quickly. Saxenda® may affect the way some medicines work and some other medicines may affect the way Saxenda® works. Tell your healthcare provider if you take diabetes medicines, especially sulfonylurea medicines or insulin.

How should I use Saxenda®?

- Use Saxenda® exactly as prescribed by your healthcare provider. Your dose should be increased after using Saxenda® for 1 week until you reach the 3 mg dose. After that, do not change your dose unless your healthcare provider tells you to.
- Saxenda® is injected 1 time each day, at any time during the day.
- You can take Saxenda® with or without food.
- Your healthcare provider should start you on a diet and exercise program when you start taking Saxenda®. Stay on this program while you are taking Saxenda®.
- Saxenda® comes in a prefilled pen.
- Your healthcare provider must teach you how to inject Saxenda® before you use it for the first time. If you have questions or do not understand the instructions, talk to your healthcare provider or pharmacist. Read the Patient Instructions for Use that come with this Medication Guide for detailed information about the right way to use your Saxenda® pen.
- Pen needles are not included. Use the Saxenda® pen with Novo Nordisk disposable needles. You may need a prescription to get pen needles from your pharmacist. Ask your healthcare provider which needle size is best for you.
- When starting a new prefilled Saxenda® pen, you must follow the “Check the Saxenda® flow with each new pen” (see the detailed Patient Instructions for Use that comes with this Medication Guide). You only need to do this 1 time with each new pen. You should also do this if you drop your pen. If you do the “Check the Saxenda® flow with each new pen” before each injection, you will run out of medicine too soon.
- Inject your dose of Saxenda® under the skin (subcutaneous injection) in your stomach area (abdomen), upper leg (thigh), or upper arm, as instructed by your healthcare provider. Do not inject into a vein or muscle.
- If you take too much Saxenda®, call your healthcare provider right away. Too much Saxenda® may cause severe nausea and vomiting.
- If you miss your daily dose of Saxenda®, use Saxenda® as soon as you remember. Then take your next daily dose as usual on the following day. Do not take an extra dose of Saxenda® or increase your dose on the following day to make up for your missed dose. If you miss your dose of Saxenda® for 3 days or more, call your healthcare provider to talk about how to restart your treatment.
- Never share your Saxenda® pen or needles with another person. You may give an infection to them, or get an infection from them.
What are the possible side effects of Saxenda®?

- Saxenda® may cause serious side effects, including: possible thyroid tumors, including cancer. See “What is the most important information I should know about Saxenda®?!”
- inflammation of the pancreas (pancreatitis). Stop using Saxenda® and call your healthcare provider right away if you have severe pain in your stomach area (abdomen) that will not go away, with or without vomiting. You may feel the pain from your abdomen to your back.
- gallbladder problems. Saxenda® may cause gallbladder problems including gallstones. Some gallbladder problems need surgery. Call your healthcare provider if you have any of the following symptoms:
  - pain in your upper stomach (abdomen)
  - yellowing of your skin or eyes (jaundice)
  - clay-colored stools
- low blood sugar (hypoglycemia) in people with type 2 diabetes mellitus who also take medicines to treat type 2 diabetes mellitus. Saxenda® can cause low blood sugar in people with type 2 diabetes mellitus who also take medicines used to treat type 2 diabetes mellitus (such as sulfonylureas). In some people, the blood sugar may get so low that they need another person to help them. If you take a sulfonylurea medicine, the dose may need to be lowered while you use Saxenda®. Signs and symptoms of low blood sugar may include:
  - shakiness
  - sweating
  - headache
  - dizziness
  - drowsiness
  - feeling jittery
  - hunger
  - fast heartbeat
  - decreased appetite
  - vomiting
  - diarrhea
  - nausea
  - dizziness
  - fast heartbeat
  - feeling jittery

Talk to your healthcare provider about how to recognize and treat low blood sugar. Make sure that your family and other people who are around you a lot know how to recognize and treat low blood sugar.

- increased heart rate. Saxenda® can increase your heart rate while you are at rest. Your healthcare provider should check your heart rate while you take Saxenda®. Tell your healthcare provider if you feel your heart racing or pounding in your chest and it lasts for several minutes when taking Saxenda®.
- kidney problems (kidney failure). Saxenda® may cause nausea, vomiting or diarrhea leading to loss of fluids (dehydration). Dehydration may cause kidney failure which can lead to the need for dialysis. This can happen in people who have never had kidney problems before. Drinking plenty of fluids may reduce your chance of dehydration.

Call your healthcare provider right away if you have nausea, vomiting, or diarrhea that does not go away, or if you cannot drink liquids by mouth.
- serious allergic reactions. Serious allergic reactions can happen with Saxenda®. Stop using Saxenda®, and get medical help right away if you have any symptoms of a serious allergic reaction. See “What is the most important information I should know about Saxenda®?”
- depression or thoughts of suicide. You should pay attention to any mental changes, especially sudden changes, in your mood, behaviors, thoughts, or feelings. Call your healthcare provider right away if you have any mental changes that are new, worse, or worry you.

The most common side effects of Saxenda® include:

- nausea
- vomiting
- diarrhea
- constipation
- headache
- decreased appetite
- upset stomach
- tiredness
- change in enzyme (lipase) levels in your blood
- dizziness
- stomach pain
- fever
- clay-colored stools

Nausea is most common when first starting Saxenda®, but decreases over time in most people as their body gets used to the medicine.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of Saxenda®. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Keep your Saxenda® pen, pen needles, and all medicines out of the reach of children.

General information about the safe and effective use of Saxenda®.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Saxenda® for a condition for which it was not prescribed. Do not give Saxenda® to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about Saxenda® that is written for health professionals.

What are the ingredients in Saxenda®?

Active ingredient: liraglutide

Inactive ingredients: disodium phosphate dihydrate, propylene glycol, phenol and water for injection

For more information, go to saxenda.com or call 1-844-363-4448.
Manufactured by: Novo Nordisk A/S, DK-2880 Bagsvaerd, Denmark
For information about Saxenda®, contact: Novo Nordisk Inc. 800 Scudders Mill Road, Plainsboro, NJ 08536 1-844-363-4448
Saxenda®, Victoza®, NovoFine®, and NovoTwist® are registered trademarks of Novo Nordisk A/S.

This Medication Guide has been approved by the U.S. Food and Drug Administration.
Instructions for Use

- Read these instructions carefully before using your Saxenda® pen.
- Do not use your pen without proper training from your healthcare provider. Make sure that you know how
to give yourself an injection with the pen before you start your
treatment.

⚠️ If you are blind or have poor eyesight and cannot
read the dose counter on the pen, do not use this pen
without help. Get help from a person with good eyesight who
is trained to use the Saxenda® pen.

- You can refresh your training at any time by watching
the online training video at www.saxenda.com.

- Start by checking your pen to make sure that it
contains Saxenda®, then look at the pictures below to
get to know the different parts of your pen and needle.

- Your pen is a prefilled dial-a-dose pen.

If you select the wrong

dose, you can turn the
dose selector forward or
backwards to the correct
dose.

⚠️ Always use the dose counter and the dose pointer to see
how many mg you select.

You will hear a “click” every time you turn the dose selector.
Do not set the dose by counting the number of clicks
you hear.

Do not use the pen scale to set the dose. It does not show
exactly how much Saxenda® is left in your pen.

Only doses of 0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg or 3 mg
can be selected with the dose selector. The selected
dose must line up exactly with the dose pointer to make sure
that you get a correct dose.

The dose selector changes the dose. Only the dose counter and
dose pointer will show how many mg you select for each dose.
You can select up to 3 mg each dose. When your pen contains
less than 3 mg the dose selector stops before 3 mg is shown.
The dose selector clicks differently when turned forward,
backwards or past the number of mg left. Do not count the pen
clicks.

 wakes up and takes
the dose counter:
- The dose counter shows you
how much Saxenda® is left in your pen.

- To see how much Saxenda® is left, use the dose counter:
Turn the dose selector until the
dose counter stops.
If it shows 3, at least 3 mg
are left in your pen. If the
dose counter stops
before 3 mg, there is not
enough Saxenda® left for
a full dose of 3 mg.

⚠️ If you need more Saxenda® than what is
left in your pen:
Only if trained or told by your
healthcare provider, you may split your dose between your
current pen and a new pen. Use a calculator to plan the doses as
instructed by your healthcare provider.

⚠️ Be very careful to calculate correctly.
If you are not sure how to split your dose using 2 pens, then
select and inject the dose you need with a new pen.

- A small drop may remain at the needle tip, but it will not be
injected.

Only check the Saxenda® flow before your first
injection with each new pen.

Step 3. Select your dose

- Turn the dose selector until the dose counter shows your dose (0.6
mg, 1.2 mg, 1.8 mg, 2.4 mg or 3 mg).

Make sure you know the
dose of Saxenda® you
should use.

If you select the wrong
dose, you can turn the
dose selector forward or
backwards to the correct
dose.

⚠️ Always use the dose counter and the dose pointer to see
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clicks.

⚠️ How much Saxenda® is
left?

The pen scale shows you
about how much Saxenda® is
left in your pen.

- A small drop may remain at the needle tip, but it will not be
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less than 3 mg the dose selector stops before 3 mg is shown.
The dose selector clicks differently when turned forward,
backwards or past the number of mg left. Do not count the pen
clicks.
• Press and hold down the dose button until the dose counter shows 0. The 0 must line up with the dose pointer. You may then hear or feel a click.

• Keep the needle in your skin after the dose counter has returned to 0 and count slowly to 6.

• If the needle is removed earlier, you may see a stream of Saxenda® coming from the needle tip. If this happens, the full dose will not be delivered.

• Remove the needle from your skin. If blood appears at the injection site, press lightly. Do not rub the area.

Always watch the dose counter to know how many mg you inject. Hold the dose button down until the dose counter shows 0.

How to identify a blocked or damaged needle?
• If 0 does not appear in the dose counter after continuously pressing the dose button, you may have used a blocked or damaged needle.

• If this happens you have not received any Saxenda® even though the dose counter has moved from the original dose that you have set.

How to handle a blocked needle?
Change the needle as described in Step 5, and repeat all steps starting with Step 1. “Prepare your pen with a new needle.” Make sure you select the full dose you need. Never touch the dose counter when you inject. This can stop the injection.

You may see a drop of Saxenda® at the needle tip after injecting. This is normal and does not affect your dose.

Step 5. After your injection
• Carefully remove the needle from the pen. Do not put the needle caps back on the needle, to avoid needle sticks.

• Place the needle in a sharps container right away to reduce the risk of needle sticks.

• Put the pen cap on your pen after each use to protect Saxenda® from light.

○ If you do not have a sharps container, follow a 1-handed needle recapping method. Carefully slip the needle into the outer needle cap. Dispose of the needle in a sharps container as soon as possible.

Never try to put the inner needle cap back on the needle. You may stick yourself with the needle.

Always remove the needle from your pen. This prevents contamination, infection, leakage of Saxenda®, and blocked needles leading to the wrong dose. If the needle is blocked, you will not inject any Saxenda®.

Always dispose of the needle after each injection.
• Do not throw away in the household trash. Put the needle and any empty Saxenda® pen or any pen used for 30 days still containing Saxenda® in a FDA-cleared sharps disposal container right away after use.

• If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
  - made of a heavy-duty plastic
  - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out upright and stable during use
  - leak-resistant
  - properly labeled to warn of hazardous waste inside the container

• When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about the safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA’s website at: http://www.fda.gov/safesharpsdisposal

• Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

Safely dispose of Saxenda® that is out of date or no longer needed.

Important
• Caregivers must be very careful when handling used needles to prevent needle sticks and cross infection.

• Never use a syringe to withdraw Saxenda® from your pen.

• Always carry an extra pen and new needles with you, in case of loss or damage.

• Always keep your pen and needles out of reach of others, especially children.

• Do not share your Saxenda® pen or needles with anyone else. You may give an infection to them or get an infection from them.

• Always keep your pen with you. Do not leave it in a car or other place where it can get too hot or too cold.

Caring for your pen
• Do not drop your pen or knock it against hard surfaces. If you drop it or suspect a problem, attach a new needle and check the Saxenda® flow before you inject.

• Do not try to repair your pen or pull it apart.

• Do not expose your pen to dust, dirt or liquid.

• Do not wash, soak, or lubricate your pen. If necessary, clean it with mild detergent on a moistened cloth.

How should I store my Saxenda® pen?
• Store your new, unused Saxenda® pens in the refrigerator at 36°F to 46°F (2°C to 8°C).

• Store your pen in use for 30 days at 59°F to 86°F (15°C to 30°C) or in a refrigerator at 36°F to 46°F (2°C to 8°C).

• The Saxenda® pen you are using should be thrown away after 30 days, even if it still has Saxenda® left in it.

• Do not freeze Saxenda®. Do not use Saxenda® if it has been frozen.

• Unused Saxenda® pens may be used until the expiration date printed on the label, if kept in the refrigerator.

• Keep Saxenda® away from heat and out of the light.

• Do not leave it in a car or knock it against hard surfaces. If

• Caring for your pen

• Place the needle in a sharps container right away to reduce the risk of needle sticks.