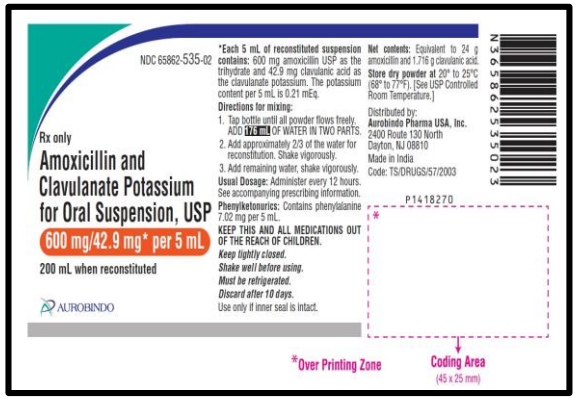

PATIENT NAME (Last, First)
1 Smith Lane, Troy NY 12180

METOPROLOL TABLET 50 MG
TAKE 1 TABLET BY MOUTH TWICE A DAY

Dr. Jones, MD March 12, 2018 RX # 2227456

XYZ Pharmacy
42 Central Avenue, Albany NY 518-486-2222

Discussion of Drug and Prescription Labeling

FDA Approved Drug Labeling

- Required to be informative and accurate
- Summary for the safe and effective use of the drug
- No promotional, false, or misleading content
- No claims or suggestions for use if evidence of safety or effectiveness is lacking
- Based on data derived from human experience

Prescription Drug Labeling Purpose

- Provides healthcare professionals the information they need to prescribe drugs appropriately
- Patient Counseling Information section is the FDA approved patient information and is written for a lay audience

Prescription Drug Labeling

- Labeling defined in 21 U.S.C 321(m)
- Includes the written and printed information often referred to as the:
  - Prescribing information
  - Package insert
  - Professional labeling
  - Information for the healthcare provider
- Requirements on content and format are outlined in 21 CFR 201.56
- Requires specific information be provided under specified heading and subheadings
- Information must be presented in the order outlined in federal regulation

Highlights of Prescribing Information

Concise, high-level summary of the drug information

Must contain the following statement: “These highlights do not include all the information needed to use (*insert name of drug product*) safely and effectively. See full prescribing information for (insert name of drug product).”

Product Names, Other Required Information	Dosage Forms and Strengths
Boxed Warning	Contraindications
Recent Major Changes	Warnings and Precautions
Indications and Usage	Adverse Reactions
Dosage and Administration	Drug Interactions
	Use in Specific Populations

Highlights of Prescribing Information

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use VICTOZA safely and effectively. See full prescribing information for VICTOZA.
VICTOZA ® (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 VICTOZA 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 , 13.1).**
- **VICTOZA is contraindicated in patients with a personal or family history of MTC 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).**

RECENT MAJOR CHANGES

Indications and Usage (1) 8/2017
Contraindications (4) 8/2017
Warnings and Precautions (5.2, 5.6, 5.7) 8/2017

INDICATIONS AND USAGE

VICTOZA is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated:

- as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (1).
- to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease (1).

Limitations of Use:

- Not for treatment of type 1 diabetes mellitus or diabetic ketoacidosis.
- Has not been studied in combination with prandial insulin.

DOSAGE AND ADMINISTRATION

- Inject subcutaneously in the abdomen, thigh or upper arm (2.1).
- Administer once daily at any time of day, independently of meals (2.2).
- Initiate at 0.6 mg per day for one week then increase to 1.2 mg. Dose can be increased to 1.8 mg for additional glycemic control (2.2).

DOSAGE FORMS AND STRENGTHS

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

CONTRAINDICATIONS

VICTOZA is contraindicated in patients with a personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2 (4).
VICTOZA is contraindicated in patients with a prior serious hypersensitivity reaction to VICTOZA or any of the product components (4).

WARNINGS AND PRECAUTIONS

- Thyroid C-cell Tumors: See Boxed Warning (5.1).
- Pancreatitis: Postmarketing reports, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis. Discontinue promptly if pancreatitis is suspected. Do not restart if pancreatitis is confirmed (5.2).
- Never share a VICTOZA pen between patients, even if the needle is changed (5.3).
- Serious Hypoglycemia: When VICTOZA is used with an insulin secretagogue (e.g. a sulfonylurea) or insulin, consider lowering the dose of the insulin secretagogue or insulin to reduce the risk of hypoglycemia (5.4).
- Renal Impairment: Postmarketing, usually in association with nausea, vomiting, diarrhea, or dehydration which may sometimes require hemodialysis. Use caution when initiating or escalating doses of VICTOZA in patients with renal impairment (5.5).
- Hypersensitivity: Postmarketing reports of serious hypersensitivity reactions (e.g., anaphylactic reactions and angioedema). Discontinue VICTOZA and promptly seek medical advice (5.6).
- Acute Gallbladder Disease: If cholelithiasis or cholecystitis are suspected, gallbladder studies are indicated (5.7).

ADVERSE REACTIONS

- The most common adverse reactions, reported in ≥5% of patients treated with VICTOZA are: nausea, diarrhea, vomiting, decreased appetite, dyspepsia, constipation (6.1).
- Immunogenicity-related events, including urticaria, were more common among VICTOZA-treated patients (0.8%) than among comparator-treated patients (0.4%) in clinical trials (6.2).

To report SUSPECTED ADVERSE REACTIONS, contact Novo Nordisk Inc. at 1-877-484-2869 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

VICTOZA delays gastric emptying. May impact absorption of concomitantly administered oral medications. (7).

USE IN SPECIFIC POPULATIONS

- Renal Impairment: No dose adjustment recommended (2.4, 8.6, 12.3).
- Pregnancy: Victoza should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus (8.1).

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 1/2018

Full Prescribing Information Content

Must contain a list of each heading and subheading required by federal regulation for the full prescribing information

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

DAILYMED

- Provides a standard, comprehensive and up-to-date look-up and download resource for drug labeling
- Online source of information about marketed prescription drugs
- Official provider of FDA prescription drug labeling information
- National Library of Medicine (NLM) provides this as a public service
- No advertisements are permitted
- Drug labeling information on this site is the most recent submitted to the Food and Drug Administration (FDA)
- https://dailymed.nlm.nih.gov/dailymed/index.cfm

Patient Specific Medication Label

- Prepared and dispensed by a pharmacist to a patient
- Based upon patient specific prescription
- Affixed to the immediate container
- Must contain the following:
    - Pharmacy name & address
    - Date prepared
    - Prescription serial number
    - Prescriber name
    - Patient name & address
    - Drug Name
    - Drug strength
    - Directions for use

SAFE RX Statute

- Required development of standardized patient centered data elements for prescription labels
- Designed to increase patient understanding and increase patient compliance with medication regimen
- Result was regulation that outlined both critical and important elements on prescription labels

Critical Elements on Prescription Label

Must be emphasized on the label by highlight, in bold type, or both

Minimum of 12 point font

Critical elements are:

- Patient Name
- Directions for use by the patient
- Drug Name
- Drug Strength

Important Elements on Prescription Label

Cannot be highlighted or in bold type

Cannot be emphasized in any way that would undermine emphasis of critical elements

Important elements are:

- Pharmacy name, address & telephone
- Patient address
- Prescriber name
- Date prepared
- Prescription serial number

SAMPLE PRESCRIPTION LABELS

MAIN PHARMACY INC. 518-474-3817
89 WASHINGTON AVENUE, ALBANY, NEW YORK 12234
RX: 2235687 Date: June 7, 2016
First Last Name
1520 Towne Plaza Drive, Lowville, NY 13367

Take 1 tablet by mouth every morning.

DrugXYZ 10 mg

Mfg: Main Pharmaceuticals Jane Smith, MD

PATIENT NAME (Last, First)
1 Smith Lane, Troy NY 12180

METOPROLOL TABLET 50 MG

TAKE 1 TABLET BY MOUTH TWICE A DAY

Dr. Jones, MD March 12, 2018 RX # 2227456

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