INSULIN-CONTAINING PRODUCTS FROM NOVO NORDISK

Please see the following pages for Tresiba®, Xultophy® 100/3.6, and Fiasp® Dosing, Storage, and Savings Information.

BASAL

TRESIBA®
insulin degludec injection 100 U/mL, 200 U/mL

100 units/mL; total of
300 units/pen; 5-pen pack[1]
NDC: 0169-2660-15

200 units/mL; total of
600 units/pen; 3-pen pack[1]
NDC: 0169-2550-13

100 units/mL; total of
1000 units/vial; 1 vial/pack[1]
NDC: 0169-2662-11

BASAL/GLP-1 RA

Xultophy® 100/3.6
insulin degludec & liraglutide injection
100 units/mL & 3.6 mg/mL

100 units/mL insulin degludec and 3.6 mg/mL liraglutide;
total of 300 units insulin degludec and 10.8 mg liraglutide; 5-pen pack[2]
NDC: 0169-2911-15

PRANDIAL

Fiasp®
insulin aspart injection
100 units/mL

100 units/mL; total of 300 units;
5-pen pack[3]
NDC: 0169-3204-15

100 units/mL; total of
300 units/pen; 5-cartridge pack[3]
NDC: 0169-3205-15

100 units/mL; total of
1000 units/vial; 1 vial/pack[3]
NDC: 0169-3201-11

Approved for use in pumps[3]

Refer to the insulin infusion pump user manual to see if Fiasp® can be used. Use in accordance with the insulin pump's Instructions for Use.

GLP-1 RA=glucagon-like peptide-1 receptor agonist.

Tresiba® Indications and Usage

Tresiba® (insulin degludec) injection is indicated to improve glycemic control in patients 1 year of age and older with diabetes mellitus.

Limitations of Use

Tresiba® is not recommended for treating diabetic ketoacidosis.

Tresiba® Important Safety Information

Contraindications

- Tresiba® is contraindicated during episodes of hypoglycemia and in patients with hypersensitivity to insulin degludec or any of the excipients in Tresiba®

Xultophy® 100/3.6 Indications and Limitations of Use

Xultophy® 100/3.6 (insulin degludec and liraglutide) injection 100 units/mL and 3.6 mg/mL is a combination of insulin degludec and liraglutide and is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

- Xultophy® 100/3.6 is not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise.
- Xultophy® 100/3.6 is not recommended for use in combination with any other product containing liraglutide or another GLP-1 receptor agonist (GLP-1 RA).
- Xultophy® 100/3.6 is not indicated for use in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.
- Xultophy® 100/3.6 has not been studied in combination with prandial insulin.

Xultophy® 100/3.6 Important Safety Information

WARNING: RISK OF THYROID C-CELL TUMORS

- **Liraglutide, one of the components of Xultophy® 100/3.6, 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 Xultophy® 100/3.6 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.**
- **Xultophy® 100/3.6 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 for MTC with the use of Xultophy® 100/3.6 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 Xultophy® 100/3.6.**

Fiasp® Indications and Usage

Fiasp® (insulin aspart injection) 100 U/mL is a rapid-acting insulin analog indicated to improve glycemic control in adult and pediatric patients with diabetes mellitus.

Fiasp® Important Safety Information

Contraindications

- Fiasp® is contraindicated during episodes of hypoglycemia and in patients hypersensitive to Fiasp® or one of its excipients.

Click here for Prescribing Information for Tresiba®.
Click here for Prescribing Information, including Boxed Warning, for Xultophy® 100/3.6.
Click here for Prescribing Information for Fiasp®.
Please see additional Important Safety Information for Tresiba®, Xultophy® 100/3.6, and Fiasp® throughout.

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		INDICATION	MAX DOSE PER INJECTION	STARTING DOSE
BASAL	TRESIBA® insulin degludec injection 100 U/mL, 200 U/mL	A long-acting human insulin analog indicated to improve glycemic control in patients 1 year of age and older with diabetes mellitus.[1]	**U-100 pen:** 80 units; 1-unit dose increments **U-200 pen:** 160 units; 2-unit increments **U-100 vial:** N/A; allows for half-unit dosing	**T1D insulin naïve[1]:** Approximately one-third to one-half of the total daily insulin dose **T2D insulin naïve[1]:** 10 units QD
BASAL/GLP-1 RA	Xultophy® 100/3.6 insulin degludec & liraglutide injection 100 units/mL & 3.6 mg/mL	A combination of insulin degludec, a long-acting human insulin analog, and liraglutide, a GLP-1 RA, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.[2]	50 units; 1-unit dose increments	**Naïve to basal insulin or a GLP-1 RA[2]:** 10 units QD
PRANDIAL	Fiasp® insulin aspart injection 100 units/mL	A rapid-acting human insulin analog indicated to improve glycemic control in adult and pediatric patients with diabetes mellitus.[3]	**3-mL pen:** 80 units; 1-unit dose increments **3-mL PenFill®:** N/A; allows for half-unit dosing **U-100 vial:** N/A; allows for half-unit dosing PenFill® cartridges are designed for use with Novo Nordisk insulin delivery devices	Individualize dosage based on patients' metabolic needs, blood glucose monitoring results, and glycemic control goal[3] Administer at the start of the meal OR within 20 minutes after starting a meal

T1D=type 1 diabetes; T2D=type 2 diabetes; QD=once daily.

Tresiba® Important Safety Information (cont'd)

Warnings and Precautions

- **Never Share a Tresiba® FlexTouch® Pen, Needle, or Syringe Between Patients, even if the needle is changed.** Patients using Tresiba® vials should never share needles or syringes with another person. Sharing poses a risk for transmission of blood-borne pathogens
- **Hyperglycemia or Hypoglycemia with Changes in Insulin Regimen:** Changes in an insulin regimen (e.g., insulin strength, manufacturer, type, or injection site or method of administration) may affect glycemic control and predispose to hypoglycemia or hyperglycemia. Repeated insulin injections into areas of lipodystrophy or localized cutaneous amyloidosis have been reported to result in hyperglycemia; and a sudden change in the injection site (to an unaffected area) has been reported to result in hypoglycemia. Make any changes to a patient's insulin regimen under close medical supervision with increased frequency of blood glucose monitoring. Advise patients who have repeatedly injected into areas of lipodystrophy or localized cutaneous amyloidosis to change the injection site to unaffected areas and closely monitor for hypoglycemia. Adjustments in concomitant anti-diabetic treatment may be needed.

Xultophy® 100/3.6 Important Safety Information (cont'd)

Contraindications

- Xultophy® 100/3.6 is contraindicated in patients with a personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2), during episodes of hypoglycemia, and in patients with hypersensitivity to Xultophy® 100/3.6, either of the active substances, or any of its excipients. Serious hypersensitivity reactions including anaphylactic reactions and angioedema have been reported with liraglutide, one of the components of Xultophy®100/3.6.

Warnings and Precautions

- **Risk of Thyroid C-cell Tumors:** If serum calcitonin is measured and found to be elevated or thyroid nodules are noted on physical examination or neck imaging, the patient should be further evaluated.

Fiasp® Important Safety Information (cont'd)

Warnings and Precautions

- **Never share a Fiasp® FlexTouch® Pen, PenFill® cartridge or PenFill® cartridge device between patients, even if the needle is changed.** Patients using Fiasp® vials must never share needles or syringes with another person. Sharing poses a risk for transmission of blood-borne pathogens.
- **Hyperglycemia or Hypoglycemia with Changes in Insulin Regimen:** Changes in an insulin regimen (e.g., insulin strength, manufacturer, type, injection site or method of administration) may affect glycemic control and predispose to hypoglycemia or hyperglycemia. Repeated insulin injections into areas of lipodystrophy or localized cutaneous amyloidosis have been reported to result in hyperglycemia; and a sudden change in the injection site (to an unaffected area) has been reported to result in hypoglycemia. Make any changes to a patient's insulin regimen under close medical supervision with increased frequency of blood glucose monitoring. Advise patients who have repeatedly injected into areas of lipodystrophy or localized cutaneous amyloidosis to change the injection site to unaffected areas and closely monitor for hypoglycemia. Adjustments in concomitant anti-diabetic treatment may be needed.

Click here for Prescribing Information for Tresiba®.
Click here for Prescribing Information, including Boxed Warning, for Xultophy® 100/3.6.
Click here for Prescribing Information for Fiasp®.
Please see additional Important Safety Information for Tresiba®, Xultophy® 100/3.6, and Fiasp® throughout.

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		DOSING CONVERSION	STORAGE	SAVINGS CARD INFORMATION[a,b]
BASAL	TRESIBA® insulin degludec injection 100 U/mL, 200 U/mL	**Adults with T1D or T2D[1]:** 1:1 conversion **Pediatric patients (≥1 year) with T1D or T2D[1]:** 80% of the total daily long- or intermediate-acting insulin unit dose	**Unopened[1]:** Refrigerate (36°F-46°F) until expiration date or store at room temperature (<86°F) for 8 weeks **Opened[1]:** Refrigerate (36°F-46°F) or store at room temperature (<86°F) for 8 weeks	 Eligible patients pay as little as $25 or no more than $99 per prescription
BASAL/GLP-1 RA	Xultophy® 100/3.6 insulin degludec & liraglutide injection 100 units/mL & 3.6 mg/mL	**Currently on basal insulin or a GLP-1 RA:** Discontinue therapy with basal insulin or liraglutide prior to initiation of Xultophy® 100/3.6[2] **Recommended starting dose[2]:** 16 units	**Prior to first use[2]:** Refrigerate (36°F-46°F) until expiration date **After first use[2]:** Refrigerate (36°F-46°F) or store at room temperature (59°F-86°F) for 21 days	Not Applicable
PRANDIAL	Fiasp® insulin aspart injection 100 units/mL	1:1 conversion from other mealtime insulins[3]	**Unopened[3]:** Refrigerate (36°F-46°F) until expiration date or store at room temperature (<86°F) for 28 days **Opened[3]:** Refrigerate (36°F-46°F) or store at room temperature (<86°F) for 28 days Once opened, DO NOT refrigerate PenFill® cartridges	 Eligible patients pay as little as $25 per prescription up to 2 years (Maximum savings of $150 per prescription.)

[a]Needles are sold separately, will need a prescription and need to be processed by a pharmacist.
[b]Eligibility and other restrictions apply. See page 6 for details.

Tresiba® Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

- **Hypoglycemia:** Hypoglycemia is the most common adverse reaction of insulin, including Tresiba®. Severe hypoglycemia can cause seizures, may be life-threatening or cause death. Hypoglycemia can impair concentration ability and reaction time; this may place the patient and others at risk in situations where these abilities are important (e.g., driving or operating other machinery). Hypoglycemia can happen suddenly and symptoms may differ in each patient and change over time in the same patient. Symptomatic awareness of hypoglycemia may be less pronounced in patients with longstanding diabetes, in patients with diabetic neuropathy, using drugs that block the sympathetic nervous system (e.g., beta-blockers) or who experience recurrent hypoglycemia. The long-acting effect of Tresiba® may delay recovery from hypoglycemia compared to shorter-acting insulins.

Xultophy® 100/3.6 Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

- **Pancreatitis:** Acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with liraglutide postmarketing. Observe patients carefully for signs and symptoms of pancreatitis (persistent severe abdominal pain, sometimes radiating to the back with or without vomiting). If pancreatitis is suspected, discontinue Xultophy® 100/3.6 promptly and if pancreatitis is confirmed, do not restart. Liraglutide, one of the components of Xultophy® 100/3.6, 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 a higher risk for development of pancreatitis on liraglutide.
- **Never Share a Xultophy® 100/3.6 Pen Between Patients,** even if the needle is changed. Sharing of the pen poses a risk for transmission of blood-borne pathogens.

Fiasp® Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

- Hypoglycemia is the most common adverse reaction of insulin, including Fiasp®, and may be life-threatening. Increase glucose monitoring with changes to: insulin dosage, co-administered glucose lowering medications, meal pattern, physical activity; and in patients with renal impairment or hepatic impairment or hypoglycemia unawareness.
- To avoid medication errors and accidental mix-ups between Fiasp® and other insulin products, instruct patients to always check the insulin label before injection.
- As with all insulins, Fiasp® use can lead to life-threatening hypokalemia, which then may cause respiratory paralysis, ventricular arrhythmia, and death. Monitor potassium levels in patients at risk for hypokalemia and treat if indicated.
- Severe, life-threatening, generalized allergy, including anaphylaxis, may occur with insulin products, including Fiasp®.

Click here for Prescribing Information for Tresiba®.
Click here for Prescribing Information, including Boxed Warning, for Xultophy® 100/3.6.
Click here for Prescribing Information for Fiasp®.
Please see additional Important Safety Information for Tresiba®, Xultophy® 100/3.6, and Fiasp® throughout.

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OTHER INSULIN PRODUCTS FROM NOVO NORDISK[4-10]

NovoLog®
insulin aspart injection 100 Units/mL

Click here for Prescribing Information for NovoLog®.

10 mL multiple-dose vial **NDC: 0169-7501-11**
ReliOn® brand **NDC: 0169-2100-11**

3 mL single-patient-use PenFill® cartridges
NDC: 0169-3303-12

3 mL single-patient-use NovoLog® FlexPen®
NDC: 0169-6339-10
ReliOn® brand **NDC: 0169-2101-25**

NovoLog® Mix 70/30
insulin aspart protamine and
insulin aspart injectable suspension 100 Units/mL

Click here for Prescribing Information for NovoLog® Mix 70/30.

10 mL multiple-dose vial **NDC: 0169-3685-12**
ReliOn® brand **NDC: 0169-2200-11**

3 mL single-patient-use NovoLog® Mix 70/30 FlexPen®
NDC: 0169-3696-19
ReliOn® brand **NDC: 0169-2201-25**

Levemir®
insulin detemir injection 100 Units/mL

Click here for Prescribing Information for Levemir®.

3 mL single-patient-use Levemir® FlexTouch®
NDC: 0169-6438-10

10 mL multiple-dose vial
NDC: 0169-3687-12

Novolin® 70/30
(human insulin isophane suspension and human insulin injection) 100 U/mL

Click here for Prescribing Information for Novolin® 70/30.

10 mL vial **NDC: 0169-1837-11**
ReliOn® brand **NDC: 0169-1837-02**

3 mL FlexPen® **NDC: 0169-3007-15**
ReliOn® brand **NDC: 0169-3007-25**

Novolin® N
(isophane insulin human suspension) 100 U/mL

Click here for Prescribing Information for Novolin® N.

10 mL vial **NDC: 0169-1834-11**
ReliOn® brand **NDC: 0169-1834-02**

3 mL FlexPen® **NDC: 0169-3004-15**
ReliOn® brand **NDC: 0169-3004-25**

Novolin® R
(insulin human injection) 100 U/mL

Click here for Prescribing Information for Novolin® R.

10 mL vial **NDC: 0169-1833-11**
ReliOn® brand **NDC: 0169-1833-02**

3 mL FlexPen® **NDC: 0169-3003-15**
ReliOn® brand **NDC: 0169-3003-25**

GlucaGen®
(glucagon) for injection 1 mg/mL

Click here for Prescribing Information for GlucaGen®.

GlucaGen® HypoKit®
NDC: 0169-7065-15
Includes: 1 single-dose vial containing 1 mg GlucaGen® (glucagon) for injection (NDC: 0169-7065-15), 1 disposable syringe containing 1 mL Sterile Water for Reconstitution

GlucaGen® Diagnostic Kit
NDC: 0597-0260-10
Includes: 1 single-dose vial containing 1 mg GlucaGen® (glucagon) for injection (NDC: 0597-0053-01), 1 vial containing 1 mL Sterile Water for Reconstitution (NDC: 0597-0265-94)

GlucaGen® 10-pack
NDC: 0597-0053-45
Includes: 10 single-dose vials, each containing 1 mg GlucaGen® (glucagon) for injection

Click here for Prescribing Information for Tresiba®.
Click here for Prescribing Information, including Boxed Warning, for Xultophy® 100/3.6.
Click here for Prescribing Information for Fiasp®.
Please see additional Important Safety Information for Tresiba®, Xultophy® 100/3.6, and Fiasp® throughout.

Fiasp® Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

- Fluid retention and heart failure can occur with concomitant use of thiazolidinediones (TZDs), which are PPAR-gamma agonists, and insulin, including Fiasp®. Patients should be observed for signs and symptoms of heart failure. If heart failure occurs, dosage reduction or discontinuation of the TZD must be considered.
- Pump or infusion set malfunctions can lead to a rapid onset of hyperglycemia and ketoacidosis. Prompt identification and correction of the cause of hyperglycemia or ketosis is necessary. Interim therapy with subcutaneous injection of Fiasp® may be required. Patients using continuous subcutaneous insulin infusion pump therapy must be trained to administer insulin by injection and have alternate insulin therapy available in case of pump failure.

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Tresiba® Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

Risk Factors for Hypoglycemia: The risk of hypoglycemia generally increases with intensity of glycemic control. The risk of hypoglycemia after an injection is related to the duration of action of the insulin and, in general, is highest when the glucose lowering effect of the insulin is maximal. As with all insulins, the glucose lowering effect time course of Tresiba® may vary among different patients or at different times in the same patients and depends on many conditions, including the area of injection as well as the injection site blood supply and temperature. Other factors which may increase the risk of hypoglycemia include changes in meal pattern, changes in level of physical activity, or changes to concomitant drugs. Patients with renal or hepatic impairment may be at higher risk of hypoglycemia. Patients and caregivers must be educated to recognize and manage hypoglycemia. In patients at higher risk for hypoglycemia and patients who have reduced symptomatic awareness of hypoglycemia, increased frequency of blood glucose monitoring is recommended.

- **Hypoglycemia Due to Medication Errors:** Accidental mix-ups between insulin products have been reported. To avoid medication errors between Tresiba® and other insulins, always instruct patients to always check the insulin label before each injection. To avoid dosing errors and potential overdose, never use a syringe to remove Tresiba® from the Tresiba® FlexTouch disposable insulin prefilled pen.
- **Hypersensitivity Reactions:** Severe, life-threatening, generalized allergy, including anaphylaxis, can occur with insulins, including Tresiba®. If hypersensitivity reactions occur, discontinue Tresiba®; treat per standard of care and monitor until symptoms and signs resolve.
- **Hypokalemia:** All insulins, including Tresiba®, cause a shift in potassium from the extracellular to intracellular space, possibly leading to hypokalemia. Untreated hypokalemia may cause respiratory paralysis, ventricular arrhythmia, and death. Monitor potassium levels in patients at risk for hypokalemia and treat if indicated.
- **Fluid Retention and Heart Failure with Concomitant Use of PPAR-gamma Agonists:** Fluid retention and heart failure can occur with concomitant use of thiazolidinediones (TZDs), which are PPAR-gamma agonists, and insulin, including Tresiba®. Patients should be observed for signs and symptoms of heart failure. If heart failure occurs, dosage reduction or discontinuation of the TZD must be considered.

Adverse Reactions

- Adverse reactions commonly associated with Tresiba® are hypoglycemia, allergic reactions, injection site reactions, lipodystrophy, pruritus, rash, edema, and weight gain

Drug Interactions

- There are certain drugs that may cause clinically significant drug interactions with Tresiba®.
  - — Drugs that may increase the risk of hypoglycemia: antidiabetic agents, ACE inhibitors, angiotensin II receptor blocking agents, disopyramide, fibrates, fluoxetine, monoamine oxidase inhibitors, pentoxifylline, pramlintide, salicylates, somatostatin analog (e.g., octreotide), sulfonamide antibiotics, GLP-1 receptor agonists, DPP-4 inhibitors, and SGLT-2 inhibitors
  - — Drugs that may decrease the blood glucose lowering effect: atypical antipsychotics (e.g., olanzapine and clozapine), corticosteroids, danazol, diuretics, estrogens, glucagon, isoniazid, niacin, oral contraceptives, phenothiazines, progestogens (e.g., in oral contraceptives), protease inhibitors, somatropin, sympathomimetic agents (e.g., albuterol, epinephrine, terbutaline), and thyroid hormones
  - — Drugs that may increase or decrease the blood glucose lowering effect: alcohol, beta-blockers, clonidine, lithium salts, and pentamidine
  - — Drugs that may blunt the signs and symptoms of hypoglycemia: beta-blockers, clonidine, guanethidine, and reserpine

Fiasp® Important Safety Information (cont'd)

Adverse Reactions

- Adverse reactions observed with Fiasp® include hypoglycemia, allergic reactions, hypersensitivity, injection site reactions, lipodystrophy, and weight gain.

Use in Specific Populations

- Pediatric patients with type 1 diabetes treated with mealtime and postmeal Fiasp® reported a higher rate of blood glucose confirmed hypoglycemic episodes compared to patients treated with NovoLog® (insulin aspart injection); the imbalance was greater during the nocturnal period. Monitor blood glucose levels closely in pediatric patients.
- Like all insulins, Fiasp® requirements may be reduced in patients with renal impairment or hepatic impairment. These patients may require more frequent blood glucose monitoring and dose adjustments.

Click here for Prescribing Information for Tresiba®.
Click here for Prescribing Information, including Boxed Warning, for Xultophy® 100/3.6.
Click here for Prescribing Information for Fiasp®.
Please see additional Important Safety Information for Tresiba®, Xultophy® 100/3.6, and Fiasp® throughout.

Xultophy® 100/3.6 Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

- **Hyperglycemia or Hypoglycemia with Changes in Insulin Regimen:** Changes in an insulin regimen (e.g., insulin strength, manufacturer, type, or injection site or method of administration) may affect glycemic control and predispose to hypoglycemia or hyperglycemia. Repeated insulin injections into areas of lipodystrophy or localized cutaneous amyloidosis have been reported to result in hyperglycemia; and a sudden change in the injection site (to an unaffected area) has been reported to result in hypoglycemia. Make any changes to a patient's insulin regimen under close medical supervision with increased frequency of blood glucose monitoring. Advise patients who have repeatedly injected into areas of lipodystrophy or localized cutaneous amyloidosis to change the injection site to unaffected areas and closely monitor for hypoglycemia. Adjustments in concomitant anti-diabetic treatment may be needed.
- **Overdose Due to Medication Errors:** Instruct patients to check the label before each injection since accidental mix-ups with insulin containing products can occur. Do not administer more than 50 units of Xultophy® 100/3.6 daily. Do not exceed the 1.8 mg maximum recommended dose of liraglutide or use with other GLP-1 RAs.
- **Hypoglycemia:** Hypoglycemia is the most common adverse reaction of insulin-containing products, including Xultophy® 100/3.6. Severe hypoglycemia can cause seizures, may be life threatening or cause death. Hypoglycemia can impair concentration ability and reaction time which may place the patient and others at risk in situations where these abilities are important. Hypoglycemia can happen suddenly and symptoms may differ in each patient and change over time in the same patient. Symptomatic awareness of hypoglycemia may be less pronounced in patients with longstanding diabetes, diabetic neuropathy, and in patients using drugs that block the sympathetic nervous system, or who experience recurrent hypoglycemia. The long-acting effect of insulin degludec may delay recovery from hypoglycemia compared to shorter acting insulins. Increase monitoring with changes to: dose, co-administered glucose lowering medications, concomitant drugs, meal pattern, physical activity; and in patients with hypoglycemia unawareness or renal or hepatic impairment.
- **Acute Kidney Injury:** Acute renal failure and worsening of chronic renal failure, which may sometimes require hemodialysis, have been reported postmarketing for liraglutide, usually in association with nausea, vomiting, diarrhea, or dehydration. Advise patients of the potential risk of dehydration due to gastrointestinal adverse reactions and take precautions to avoid fluid depletion.
- **Hypersensitivity and Allergic Reactions:** Severe, life-threatening, generalized allergy, including anaphylaxis, angioedema, bronchospasm, hypotension, and shock can occur with insulins, including Xultophy® 100/3.6. There have been postmarketing reports of serious hypersensitivity reactions (e.g. anaphylactic reactions and angioedema) in patients treated with liraglutide, one of the components of Xultophy® 100/3.6. If a hypersensitivity reaction occurs, discontinue and treat promptly per standard of care, and monitor until signs and symptoms resolve. Anaphylaxis and angioedema have been reported with other GLP-1 RAs. Use caution in a patient with a history of anaphylaxis or angioedema with other GLP-1 RAs because it is unknown whether such patients will be predisposed to these reactions with Xultophy® 100/3.6.
- **Acute Gallbladder Disease:** Acute events of gallbladder disease such as cholelithiasis or cholecystitis have been reported in GLP-1 receptor agonist trials and postmarketing. In a cardiovascular outcomes trial (LEADER trial) 3.1% of patients treated with liraglutide, one of the components of Xultophy® 100/3.6, versus 1.9% of placebo treated patients reported an acute event of gallbladder disease, such as cholelithiasis or cholecystitis. If cholelithiasis is suspected, gallbladder studies and appropriate clinical follow-up are indicated.
- **Hypokalemia:** All insulin containing products, including Xultophy® 100/3.6 can lead to life-threatening hypokalemia, which may then cause respiratory paralysis, ventricular arrhythmia, and death. Monitor potassium levels in patients at risk for hypokalemia and treat if indicated.
- **Fluid Retention and Congestive Heart Failure:** Patients using insulin containing products, including Xultophy® 100/3.6, with thiazolidinediones (TZDs) should be observed for signs and symptoms of heart failure. If heart failure develops, dosage reduction or discontinuation of the TZD must be considered.

Adverse Reactions

- The most common adverse reactions, reported in ≥5% of patients treated with Xultophy® 100/3.6 are nasopharyngitis, headache, nausea, diarrhea, increased lipase and upper respiratory tract infection.

Drug Interactions

- Certain drugs may affect glucose metabolism, requiring dose adjustment and close monitoring of blood glucose. The signs and symptoms of hypoglycemia may be reduced or absent in patients taking anti-adrenergic drugs (e.g., beta-blockers, clonidine, guanethidine, and reserpine).
- Liraglutide-containing products, including Xultophy® 100/3.6, cause a delay of gastric emptying, and thereby have the potential to impact the absorption of concomitantly administered oral medications. Caution should be exercised when oral medications are concomitantly administered with liraglutide-containing products.

Use in Specific Populations

- Xultophy® 100/3.6 should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

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NOVO NORDISK SAVINGS CARD

Eligibility and Restrictions:

In order to redeem this offer patient must have a valid prescription for the brand being filled. A valid Prescriber ID# is required on the prescription. Patient is not eligible if he/she is enrolled in any federal or state health care program with prescription drug coverage, such as Medicaid, Medicare, Medigap, VA, DOD, TRICARE, or any similar federal or state health care program (each a Government Program), or where prohibited by law. Patient must be enrolled in a commercial insurance plan. The brand and the prescription being filled must be covered by the patient's commercial insurance plan. Offer excludes full cash-paying patients. This offer may not be redeemed for cash. This offer is not valid when the entire cost of your prescription drug is eligible to be reimbursed by a commercial insurance plan or other commercial health or pharmacy benefit programs. By using this offer, you are certifying that you meet the eligibility criteria and will comply with the terms and conditions described herein and will not seek reimbursement for any benefit received through this card. Novo Nordisk's Eligibility and Restrictions, and Offer Details may change from time to time, and for the most recent version, please visit http://www.novocare.com/eligibility/diabetes-savings-card.html and https://www.novocare.com/eligibility/tresiba-savings-card.html. Re-confirmation of information may be requested periodically to ensure accuracy of data and compliance with terms. Patients with questions about the Savings Card offer may call 1-877-304-6855.

This offer is valid only in the United States and its territories, unless prohibited by law, and may be redeemed at participating retail pharmacies. Availability of the Savings Offer in Massachusetts will be dependent upon state law in effect at the time patient presents the Savings Offer when paying for the covered medications.

Cash Discount Cards and other non-insurance plans are not valid as primary insurance under this offer. If the patient is eligible for drug benefits under any such program, the patient cannot use this offer. This Savings Card cannot be combined with any coupon, certificate, voucher, or similar offer.

Patient is responsible for complying with any insurance carrier copayment disclosure requirements, including disclosing any savings received from this program. It is illegal to (or offer to) sell, purchase, or trade this offer.

This program is managed by ConnectiveRx on behalf of Novo Nordisk. The parties reserve the right to rescind, revoke or amend this offer without notice at any time.

Offer Details:

This offer is good for eligible patients purchasing up to a 90-day supply.

(a) **FIASP® (insulin aspart injection) 100 U/mL, NOVOLOG® (insulin aspart) injection 100 U/mL, NOVOLOG® MIX 70/30 (insulin aspart protamine and insulin aspart) injectable suspension 100 U/mL**: Pay as little as ("PALA") $25 per 30-day, $50 per 60-day, or $75 per 90-day supply for the first brand for up to 24 months from the date of Savings Card activation, subject to a maximum savings of $150 per 30-day ("Savings Benefit"), $300 per 60-day, or $450 per 90-day supply.

(b) **TRESIBA® (insulin degludec) injection 100 U/mL or 200 U/mL**: Pay as little as ("PALA") $25 per 30-day, $50 per 60-day, or $75 per 90-day supply, subject to a maximum savings of $150 per 30-day supply, $300 per 60-day supply or $450 per 90-day supply, or pay no more than ("PNMT") $99 depending on insurance coverage for up to 24 months from date of Savings Card Activation. If you are commercially insured with drug coverage and your insurance co-pay is less than or equal to $175, you will receive a maximum benefit of $150 per 30-day supply, $300 per 60-day supply or $450 per 90-day supply. If you are commercially insured without drug coverage, you will pay no more than $99 per 35mL. Offer covers up to 150 mL of medication per calendar month.

Pharmacist:

When you apply this offer, you are certifying that you have not submitted a claim for reimbursement under any Government Program for this prescription, or where prohibited by law. Participation in this program must comply with all applicable laws and regulations as a pharmacy provider. By participating in this program, you are certifying that you will comply with the eligibility criteria, and terms and conditions described herein. You also certify that you will not seek reimbursement for any benefit received through this card.

Fiasp®, NovoLog®, and NovoLog® Mix 70/30 pharmacist instructions for a patient with an Eligible Third Party:

Submit the claim to the primary Third Party Payer first, then submit the balance due to CHANGE HEALTHCARE as a Secondary Payer COB [coordination of benefits] with patient responsibility amount and a valid Other Coverage Code, (e.g. 8). The patient is responsible initially for the PALA amount and the card pays up to the Savings Benefit. Offer excludes full cash-paying patients. Reimbursement will be received from CHANGE HEALTHCARE. For any questions regarding CHANGE HEALTHCARE online processing, please call the Help Desk at 1-800-433-4893.

Tresiba® pharmacist instructions for a patient with an Eligible Third Party:

Submit the claim to the primary Third Party Payer first, then submit the balance due to SS&C Health as a Secondary Payer as a co-pay only billing using BIN 019158 and a valid Other Coverage Code (e.g. 8). The patient is responsible initially for the PALA amount and the card pays up to the Savings Benefit. Reimbursement will be received from SS&C Health.

Tresiba® pharmacist instructions for a cash-paying patient:

Submit the claim to SS&C Health using BIN 019158. A valid Other Coverage Code (e.g. 1) is required. The patient is responsible for the first $99 per 35 mL (maximum of 150 mL per calendar month) and reimbursement will be received from SS&C Health.

For any questions regarding SS&C online processing, please call the Pharmacy Help Desk at 1-844-373-0987.

References: 1. Tresiba [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; July 2022. **2.** Xultophy [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; June 2022. **3.** Fiasp [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; December 2019. **4.** NovoLog [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; October 2021. **5.** NovoLog Mix [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; April 2021. **6.** Levemir [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; July 2022. **7.** Novolin 70/30 [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; December 2019. **8.** Novolin N [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; December 2019. **9.** Novolin R [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; December 2019. **10.** GlucaGen [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; March 2021.

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