ACCIDENTAL MIX-UPS

Increased carry.
Administer only under medical supervision.

5.7 Fluid Retention and Heart Failure with Concomitant use of thiazolidinediones (TZDs): Observe for signs and symptoms of heart failure, consider dosage reduction or discontinuation if heart failure occurs (5.7).

5.6 Hypersensitivity and Allergic Reactions

5.5 Hypokalemia: May be life-threatening. Monitor potassium levels in patients at risk for hypokalemia and treat if indicated (5.5).

5.4 Hypoglycemia due to medication errors: Accidental mix-ups between insulin products can occur. Instruct patients to check insulin labels before injection (5.4).

5.3 Hypoglycemia: May be life-threatening. Monitor blood glucose (7).

5.2 Hyperglycemia or Hypoglycemia with Changes in Insulin Regimen: Carry out under close medical supervision and increase frequency of blood glucose monitoring (5.2).

5.1 Hyper- or hypoglycemia with changes in insulin regimen: Carry out under close medical supervision and increase frequency of blood glucose monitoring (5.2).

4 CONTRAINDICATIONS

• During episodes of hypoglycemia (4).
• Hypersensitivity to insulin aspart or one of the excipients in FIAP® (4).

3 WARNINGS AND PRECAUTIONS

• Never share a FIAP® FlexTouch® pen, PenFill® cartridge or PenFill® cartridge device between patients, even if the needle is changed (5.1).
• Hyper- or hypoglycemia with changes in insulin regimen: Carry out under close medical supervision and increase frequency of blood glucose monitoring (5.2).

2 DOSAGE AND ADMINISTRATION

• Individualize and adjust the dosage of FIAP® based on route of administration, individual’s metabolic needs, blood glucose monitoring results and glycemic control goal (2.2).
• Dosage adjustments may be needed when switching from another insulin, with changes in physical activity, changes in concurrent medications, changes in meal patterns, changes in renal or hepatic function or during acute illness (2.2).
• Subcutaneous injection (2.2):
  • Inject at the start of a meal or within 20 minutes after starting a meal into the abdomen, upper arm, or thigh.
  • Rotate injection sites within the same region.
  • Should generally be used in regimens with an intermediate- or long-acting insulin.
• Intravenous infusion: Administer only under medical supervision after diluting to concentrations from 0.5 to 1 unit/mL insulin aspart in infusion systems using polypropylene infusion bags (2.2).
2. Severe, life-threatening, generalized allergy, including anaphylaxis, death, or anaphylactic shock, if hypersensitivity reactions occur, discontinue FIASP. If hypersensitivity reactions occur, treat per standard of care and monitor until symptoms and signs resolve.

3. Rotating injection sites within the same region from one injection to the next to reduce the risk of lipodystrophy (see Adverse Reactions (6.1)).

4. Instruct patients on basal-bolus treatment who forget a mealtime subcutaneous injection at the start of a meal or within 20 minutes after starting a meal subcutaneously into the abdomen, upper arm, or thigh.

5. The following adverse reactions are also discussed elsewhere:
   - Hypoglycemia (see Warnings and Precautions (5.2, 5.3) and Drug Interactions (7)).
   - Hypersensitivity and allergic reactions (see Warnings and Precautions (5.6)).

6. Clinical Trial Experience
   - Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug, and may not reflect the rates actually observed in clinical practice.

7. For FIASP-treated subjects than comparator-treated subjects.

8. There is some indication that Thiazolidinediones (TZDs), which are peroxisome proliferator-activated receptor (PPAR)-gamma agonists, can cause dose-related fluid retention, particularly when used in combination with insulin.

9. Fluid retention may lead to or exacerbate heart failure. Patients treated with insulin, including FIASP, and a PPAR-gamma agonist should be observed for signs and symptoms of heart failure. If heart failure develops, it should be managed according to current standards of care, and discontinuation or dose reduction of the PPAR-gamma agonist must be considered.

10. Patients must be educated to recognize and manage hypoglycemia.

11. 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. The timing of hypoglycemia usually reflects the time-action profile of the administered insulin formulation. As with all insulin preparations, the glucose lowering effect time course of FIASP may vary in different individuals or at different times in the same individual and depends on many conditions, including the area of injection as well as the injection site blood supply and temperature (see Clinical Pharmacology (12.3)).

12. Other factors which may increase the risk of hypoglycemia include changes in meal pattern (e.g., macronutrient content or timing of meals), changes in physical activity, or changes to co-administered medication (see Drug Interactions (7)).

13. Patients with renal or hepatic impairment may be at higher risk of hypoglycemia.

14. Patients and caregivers must be educated to recognize and manage hypoglycemia.

15. Self-monitoring of blood glucose plays an essential role in the prevention and management of hypoglycemia. In patients at higher risk for hypoglycemia, patients who have reduced symptomatic awareness of hypoglycemia, increased frequency of blood glucose monitoring is recommended.

16. FIASP® is contraindicated in patients who have had severe, life-threatening, generalized allergy, including anaphylaxis, death, or anaphylactic shock, if hypersensitivity reactions occur, discontinue FIASP. If hypersensitivity reactions occur, treat per standard of care and monitor until symptoms and signs resolve.

17. FIASP® is contraindicated in patients who have had hypersensitivity reactions to insulin aspart or one of the excipients in FIASP (see Warnings and Precautions (5.6)).
Severe, life-threatening, generalized allergy, including anaphylaxis, generalized skin reactions, angioedema, bronchospasm, hypoten- sion, and shock may occur with any insulin, including FIASP®, and may be life threatening [see Warnings and Precautions (5.6)]. In the clinical program, generalized hypersensitivity reactions (manifested by generalized skin rash and facial edema) was reported in 0.4% of patients treated with FIASP®. Allergic skin manifestations reported with FIASP® in 1.7% of patients from the clinical program include eczema, rash, rash pruritic, urticaria and dermatitis.

Lipodystrophy
Administration of insulin, including FIASP®, has resulted in lipo- hypertrophy (enlargement or thickening of tissue) and lipodystrophy (depression in the skin). In the clinical program, lipodystrophy was reported in 0.4% of patients treated with FIASP® [see Dosage and Administration (2.2)].

Injection Site Reactions
As with other insulin therapy, patients may experience rash, redness, inflammation, bruising or itching at the site of FIASP® injection. These reactions usually resolve in a few days to a few weeks, but in some occasions, may require discontinuation of FIASP®. In the clinical program, injection site reactions occurred in 1.6% of patients treated with FIASP®. In Study A, patients with type 1 diabetes treated with FIASP® reported 2.2% injection site reactions.

Weight Gain
Weight gain can occur with insulin therapy, including FIASP®, and has been attributed to the anabolic effects of insulin and the decrease in glucosuria. In Study A, patients with type 1 diabetes treated with FIASP® gained an average of 0.7 kg and in Study B, patients with type 2 diabetes treated with FIASP® gained an average of 2.7 kg.

Peripheral Edema
Insulin, including FIASP®, may cause sodium retention and edema, particularly if previous poor metabolic control is improved by intensified insulin therapy. In the clinical program, peripheral edema occurred in 0.8% of patients treated with FIASP®.

6.2 Immunogenicity
As with all therapeutic proteins, there is a potential for immunoge- nicity. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay and may be influenced by several factors such as: assay methodology, sample handling, timing of sample collection, concomitant medication, and underlying disease. For these reasons, comparison of the incidence of antibodies to FIASP® in the studies described below with the incidence of antibodies in other studies or to other products may be misleading.

In a 26-week study in adult subjects with type 1 diabetes (Study A [see Clinical Studies (14)]), among the 763 subjects who received FIASP®, 97.2% were positive for cross-reacting anti-insulin antibodies (AIR) at least once during the study, and 90.3% were positive at baseline. A total of 24.8% of patients who received FIASP® were positive for anti-drug (insulin aspart) antibodies (ADA) at least once during the study, including 17.3% that were positive at baseline.

7 DRUG INTERACTIONS
Table 4 includes clinically significant drug interactions with FIASP®.

Table 4. Clinically Significant Drug Interactions with FIASP®

<table>
<thead>
<tr>
<th>Drugs</th>
<th>Drugs That May Increase the Risk of Hypoglycemia</th>
<th>Drugs That May Decrease the Blood Glucose Lowering Effect of FIASP®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drugs:</td>
<td>Antidiabetic agents, ACE inhibitors, angiotensin receptor blocking agents, diisopropamide, insulin sensitizers, metformin, pioglitazone, saxagliptin, sitagliptin, voglibose, and warfarin.</td>
<td>Drugs: Atrial antipsychotics (e.g., olanzapine and clozapine), corticosteroids, dexamethasone, diuretics, estrogens, glucocorticoids, heparin, nicotine, oral contraceptives, phenothiazines, progestogens (e.g., in oral contraceptives), protease inhibitors, statins, sympathomimetic agents (e.g., albuterol, ephedrine, terbutaline), and thyroid hormones.</td>
</tr>
<tr>
<td>Intervention:</td>
<td>Dose reductions and increased frequency of glucose monitoring may be required when FIASP® is co-administered with these drugs.</td>
<td>Dose increases and increased frequency of glucose monitoring may be required when FIASP® is co-administered with these drugs.</td>
</tr>
</tbody>
</table>

Table 3. Proportion (%) of Patients with Type 1 Diabetes and Type 2 Diabetes Experiencing at Least One Episode of Severe Hypoglycemia in Adult Clinical Trials

<table>
<thead>
<tr>
<th>Study A (Type 1)</th>
<th>Study B (Type 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metuline FIASP® + insulin detemir (N=386)</td>
<td>Postmeal FIASP® + insulin detemir (N=377)</td>
</tr>
<tr>
<td>Severe hypoglycemia*</td>
<td>6.7</td>
</tr>
</tbody>
</table>

*Severe hypoglycemia: an episode requiring assistance of another person to actively administer carbohydrate, glucagon, or other resuscitative actions.

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Risk Summary
There are no available data with FIASP® in pregnant women to inform a drug-associated risk for major birth defects and miscarriage. Available information from published randomized controlled trials with insulin aspart use during the second trimester of pregnancy have not reported an association with insulin aspart and major birth defects or adverse maternal and fetal outcomes [see Data]. There are risks to the mother and fetus associated with poorly controlled diabetes in pregnancy [see Clinical Considerations].

In animal reproduction studies, administration of subcutaneous insulin aspart to pregnant rats and rabbits during the period of organogenesis did not cause adverse developmental effects at exposures 8- to 10-fold to human exposure to insulin aspart to pregnant rats and rabbits at a dose of 50 units/kg/day, but in rabbits at a dose of 5 units/kg/day. These doses are approximately 8 times the human subcutaneous dose of 1.0 unit/kg/day (based on human exposure equivalents). No significant effects were observed in rats at a dose of 50 units/kg/day and in rabbits at a dose of 5 units/kg/day. Nevertheless, caution should be exercised when FIASP® is administered to pregnant women to inform the drug-associated risk for major birth defects and miscarriage. These effects were similar to those observed in rats administered regular human insulin [see Data].

The estimated background risk of major birth defects is 6-10% in women pre-gestational diabetes with a HbA1c >7% and has been reported to be as high as 20-25% in women with a HbA1c >10%. The estimated background risk of miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2.4- and 15-20%, respectively.

Clinical Considerations
Diabetes-Associated Maternal and/or Embryo-Fetal Risk
Poorly controlled diabetes in pregnancy increases the risk for maternal diabetic ketoacidosis, preclampsia, spontaneous abortions, preterm delivery, stillbirth and delivery complications. Poorly controlled diabetes increases the risk for maternal major birth defects, stillbirth, birth, and macroscopic morbidity.

Data
Human Data
Published data from 5 randomized controlled trials of 441 pregnant women with diabetes mellitus treated with insulin aspart starting during the late 2nd trimester of pregnancy did not identify an association of insulin aspart with major birth defects or adverse maternal or fetal outcomes. However, these studies cannot definitively establish the absence of any risk because of methodological limitations, including a variable duration of treatment and small size of the majority of the trials.

Animal Data
Fertility, embryo-fetal and pre-and postnatal developmental studies have been performed with insulin aspart and regular human insulin in rats and rabbits. In a combined fertility and embryo-fetal development study in rats, insulin aspart was administered before mating, during mating, and throughout pregnancy. Further, in a pre- and postnatal development study insulin aspart was given throughout pregnancy and during lactation to rats. In an embryo- fetal development study insulin aspart was given to female rabbits during organogenesis. The effects of insulin aspart did not differ from those observed with subcutaneous regular human insulin.

Insulin aspart, like human insulin, caused pre- and post-implanta- tion losses and visceral/skeletal abnormalities in rats at a dose of 200 units/kg/day (approximately 32 times the human subcutaneous dose of 1.0 unit/kg/day, based on human exposure equivalents) and in rabbits at a dose of 10 units/kg/day (approximately 3 times the human subcutaneous dose of 1.0 unit/kg/day, based on human exposure equivalents). No significant effects were observed in rats at a dose of 50 units/kg/day and in rabbits at a dose of 3 units/kg/day. Nevertheless, caution should be exercised when FIASP® is administered to pregnant women to inform the drug-associated risk for major birth defects and miscarriage. These effects were similar to those observed in rats administered regular human insulin [see Data].

The estimated background risk of major birth defects is 6-10% in women with pre-gestational diabetes with a HbA1c >7% and has been reported to be as high as 20-25% in women with a HbA1c >10%. The estimated background risk of miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2.4- and 15-20%, respectively.

10 OVERDOSE
Excess insulin administration may cause hypoglycemia and hypokalemia [see Warnings and Precautions (5.3, 5.5)]. Mild episodes of hypoglycemia usually can be treated with oral glucose. Adjustments in drug dosage, meal patterns, or exercise, may be needed. More severe episodes with coma, seizure or neurologic impairment may be treated with intramuscular/ subcutaneous glucagon or concentrated intravenous glucose.

Sustained carbohydrate intake and observation may be necessary because hypoglycemia may recur after apparent clinical recovery. Hypokalemia must be corrected appropriately.

11 DESCRIPTION
FIASP® (insulin aspart injection) is a rapid-acting insulin analog for subcutaneous or intravenous administration used to lower blood glucose. The insulin aspart analog is homologous with regular human insulin with the exception of a single substitution of the amino acid proline by aspartic acid in position B28, and is produced by recombinant DNA technology utilizing Saccharomyces cerevisiae. Insulin aspart has the empirical formula C_{22}H_{31}F_{3}N_{4}O_{7}S_{5} and a molecular weight of 5825.8 daltons.
The efficacy of FIASP® was evaluated in 3 randomized, active-controlled trials of 18 to 26 weeks duration. In total 1244 adult subjects were randomized to FIASP® (N=763 with type 1 diabetes; N=461 with type 2 diabetes). In adult patients with type 1 diabetes, mealtime FIASP® and postmeal FIASP® led to non-inferior glycemic control compared to mealtine NovoLog®, both in adult patients with type 1 diabetes. In adult patients with type 2 diabetes, mealtime FIASP® provided non-inferior glycemic control compared to mealtine NovoLog®, both in combination with metformin. In addition, mealtime FIASP® in a basal-bolus regimen with metformin also provided statistically significant improvement in the overall glycemic control compared to basal insulin therapy alone with metformin in adult patients with type 2 diabetes.

14.2 Type 1 Diabetes - Adults

Study A (NCT01831765): FIASP® added to insulin detemir in patients with Type 1 DM inadequately controlled at baseline. The efficacy of FIASP® was evaluated in a 26-week, randomized, active-controlled, treat-to-target, multicenter trial in 1143 adult patients with type 1 diabetes inadequately controlled at baseline. Patients were randomized to either blinded mealtime FIASP® (N=381), blinded mealtime NovoLog® (N=380), or open-label postmeal FIASP® (N=382), all in combination with once or twice daily insulin detemir at randomization. Patients were switched to FIASP® on a unit to unit basis. Mealtime FIASP® or NovoLog® was injected 0-2 minutes before the meal, and postmeal FIASP® was injected 20 minutes after the start of the meal. The mean age of the randomized subjects was 44.4 years and mean duration of diabetes was 19.9 years. 59% were male, 93% were White, 2% were Black or African American, and 7% were Hispanic. The mean BMI was 26.7 kg/m². After 26 weeks of treatment, treatment difference in HbA1c reduction from baseline between mealtime FIASP® compared to mealtime NovoLog®, and the treatment difference between postmeal FIASP® compared to mealtime NovoLog® met the pre-specified non-inferiority margin (0.4%). See Table 6. Insulin doses were similar among study arms at baseline and at the end of the trial.

14.3 Type 2 Diabetes - Adults

Study B (NCT01891192): FIASP® added to basal insulin and oral antidiabetics in patients with Type 2 DM inadequately controlled at baseline on basal insulin and oral antidiabetics. The efficacy of FIASP® was evaluated in a 26-week randomized, double-blind, active controlled, treat-to-target, multicenter, multinational parallel group trial in 693 adult patients with type 2 diabetes who were inadequately controlled at baseline on basal insulin and oral antidiabetic therapy and had been on these therapies for at least 6 months. Patients were randomized to either mealtime FIASP® or to mealtime NovoLog®, both in combination with oral glinide and metformin in a basal-bolus regimen. Mealtime FIASP® or mealtime NovoLog® was injected 0-2 minutes before the meal. The mean age of the randomized subjects was 59.5 years and the mean duration of diabetes was 12.7 years. 49% were male, 81% were White, 6% were Black or African American, and 6% were Hispanic. The mean BMI was 31.2 kg/m². After 26 weeks of treatment, the treatment difference in HbA1c reduction from baseline between mealtime FIASP® and mealtime
NovoLog®, both in combination with insulin glargine and metformin, met the pre-specified non-inferiority margin (0.4%). See Table 7. Insulin doses were similar among study arms at the end of the trial.

Table 7. Results from Study B: 26-Week Trial of Mealtime FIASP® Compared to Mealtime NovoLog®, Both Used in Combination with Insulin Glargine and Metformin, in Adults with Type 2 Diabetes

<table>
<thead>
<tr>
<th>Mealtimes</th>
<th>FIASP® Insulin glargine + metformin</th>
<th>Mealtimes NovoLog® Insulin glargine + metformin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of subjects randomized (N)</td>
<td>345</td>
<td>344</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>Baseline</td>
<td>8.0</td>
</tr>
<tr>
<td>Adjusted change from baseline</td>
<td>-1.38</td>
<td>-0.76</td>
</tr>
<tr>
<td>Estimated treatment difference vs. NovoLog® [95%CI]*</td>
<td>-0.02 [-0.15; 0.10]</td>
<td></td>
</tr>
</tbody>
</table>

Baseline is based on the mean of the observed last available values prior to randomization.

*Tested for non-inferiority

11.9% of subjects on the Mealtime FIASP® arm and 10.2% of subjects on the Mealtime NovoLog® arm were missing the final HbA1c assessment.

Study C (NCT018550615): FIASP® added to basal insulin and metformin in patients with Type 2 DM inadequately controlled at baseline on basal insulin and metformin

The efficacy of FIASP® was evaluated in an 18-week randomized, open-label, parallel group trial in 236 adult patients with type 2 diabetes who were inadequately controlled on basal insulin and metformin therapy, either with or without oral antidiabetic therapy, for at least 3 months. Patients were randomized to either mealtime FIASP® in addition to basal insulin and metformin or to continuing basal insulin and metformin therapy without FIASP®. The basal insulins used in both treatment arms were insulin glargine, insulin detemir or NPH. All patients were also required to be on ≥1000 mg metformin treatment at baseline.

The mean age of the trial population was 57.4 years and the mean duration of diabetes was 11.3 years. 48% were male, 70% were White, 4% were Black or African American, and 37% were Hispanic. The mean BMI was 30.8 kg/m². After 18 weeks of treatment, addition of FIASP® to basal insulin and metformin statistically significantly reduced HbA1c compared to continuing basal insulin and metformin therapy without addition of FIASP® (Table 8).

Table 8. Results from Study C: 18-Week Trial of Mealtime FIASP® in Adults with Type 2 Diabetes Inadequately Controlled at Baseline on Basal Insulin and Metformin

<table>
<thead>
<tr>
<th>FIASP® + basal insulin + metformin</th>
<th>Basal insulin + metformin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of subjects randomized (N)</td>
<td>116</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>Baseline</td>
</tr>
<tr>
<td>Adjusted change from baseline</td>
<td>-1.16</td>
</tr>
<tr>
<td>Estimated treatment difference vs. basal insulin+metformin [95%CI]</td>
<td>-0.94 [-1.17; -0.72]</td>
</tr>
<tr>
<td>Proportion of patients Achieving HbA1c &lt; 7% at Trial End</td>
<td>60.3%</td>
</tr>
</tbody>
</table>

Baseline is based on the mean of the observed last available values prior to randomization.

* p < 0.0001, 1-sided p-value evaluated at 2.5% level for superiority.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

FIASP® (insulin aspart injection) 100 units of insulin aspart per mL (U-100) is available as a clear and colorless solution in the following presentations and packaging configurations:

- Carton of 10 mL multiple-dose vials NDC 0169-3201-11
- Carton of five 3 mL single-patient use FIASP® FlexTouch® pen NDC 0169-3204-15
- Carton of five 3 mL single-patient-use PenFil® cartridges NDC 0169-3205-15
- The FIASP® FlexTouch® pen dials in 1 unit increments. *FIASP® PenFil® cartridges are designed for use with Novo Nordisk insulin delivery devices.

16.2 Recommended Storage

Unused FIASP® vials should be stored between 2° to 8°C (36° to 46°F) in a refrigerator, but not in or near a freezing compartment. FIASP® should not be exposed to excessive heat or light and must never be frozen. Do not freeze FIASP® and do not use FIASP® if it has been frozen. FIASP® should not be drawn into a syringe and stored for later use. Only use the product if it has a clear and almost colorless appearance.

Keep the cap on the pen in order to protect from light. Keep unused vials and FIASP® FlexTouch® in the carton so they will stay clean and protected from light.

Always remove the needle after each injection and store FIASP® FlexTouch® without a needle attached. This prevents contamination and/or infection, or leakage of insulin, and will ensure accurate dosing. Always use a new needle for each injection to prevent contamination.

The storage conditions for vials and FIASP® FlexTouch® pens are summarized in Table 9.

Table 9. Storage Conditions for Vial, FIASP® FlexTouch®, and PenFil® Cartridges

<table>
<thead>
<tr>
<th>FIASP® presentation</th>
<th>Not in-use (unopened)</th>
<th>In-use (opened)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Room Temperature (below 30°C)</td>
<td>Refrigerated (2°C to 8°C)</td>
<td>Refrigerated (2°C to 8°C)</td>
</tr>
<tr>
<td>10 mL vial</td>
<td>28 days</td>
<td>Until expiration date</td>
</tr>
<tr>
<td>3 mL FIASP® FlexTouch®</td>
<td>28 days</td>
<td>Until expiration date</td>
</tr>
<tr>
<td>3 mL PenFil® cartridges</td>
<td>28 days</td>
<td>Until expiration date</td>
</tr>
</tbody>
</table>

Storage of FIASP® in Intravenous Infusion Fluids:

Infusion bags prepared as indicated under Dosage and Administration (2.2) are stable at room temperature for 24 hours.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-Approved Patient Labeling (Patient Information and Instructions for Use).

Never Share a FIASP® FlexTouch® Pen Device, PenFil® Cartridge, or PenFil™ Cartridge Device Between Patients

Advise patients that they should never share a FIASP® FlexTouch® pen device, PenFil® cartridge or PenFil™ cartridge devices with another person, even if the needle is changed, because doing so carries a risk for transmission of blood-borne pathogens. Advise patients using FIASP® vials not to share needles or syringes with another person. Sharing poses a risk for transmission of blood-borne pathogens [see Warnings and Precautions (5.1)].

Hypoglycemia

Inform patients that hypoglycemia is the most common adverse reaction with insulin. Instruct patients on self-management procedures including glucose monitoring, proper injection technique, and management of hypoglycemia and hyperglycemia, especially at initiation of FIASP® therapy. Instruct patients on handling of special situations such as intercurrent conditions (illness, stress, or emotional disturbances), an inadequate or skipped insulin dose, inadvertent administration of an increased insulin dose, inadequate food intake, and skipped meals. Inform patients on the management of hypoglycemia [see Warnings and Precautions (5.3)].

Instruct patients that their ability to concentrate and react may be impaired as a result of hypoglycemia. Advise patients who have frequent hypoglycemia or reduced or absent warning signs of hypoglycemia to use caution when driving or operating machinery.

Hypersensitivity Reactions

Advise patients that hypersensitivity reactions have occurred with FIASP®. Inform patients on the symptoms of hypersensitivity reactions [see Warnings and Precautions (5.6)].

Hypoglycemia due to Medication Errors

Instruct patients to always check the insulin label before each injection to avoid mix-ups between insulin products.

Women of Reproductive Potential

Advise patients to inform their health care professional if they are pregnant or are contemplating pregnancy.

Instruct patients on the management of hypoglycemia to use caution when driving or operating machinery.

Hypoglycemia

Inform patients that hypoglycemia is the most common adverse reaction with insulin. Instruct patients on self-management procedures including glucose monitoring, proper injection technique, and management of hypoglycemia and hyperglycemia, especially at initiation of FIASP® therapy. Instruct patients on handling of special situations such as intercurrent conditions (illness, stress, or emotional disturbances), an inadequate or skipped insulin dose, inadvertent administration of an increased insulin dose, inadequate food intake, and skipped meals. Inform patients on the management of hypoglycemia [see Warnings and Precautions (5.3)].

Inform patients that their ability to concentrate and react may be impaired as a result of hypoglycemia. Advise patients who have frequent hypoglycemia or reduced or absent warning signs of hypoglycemia to use caution when driving or operating machinery.

Hypersensitivity Reactions

Advise patients that hypersensitivity reactions have occurred with FIASP®. Inform patients on the symptoms of hypersensitivity reactions [see Warnings and Precautions (5.6)].

Hypoglycemia due to Medication Errors

Instruct patients to always check the insulin label before each injection to avoid mix-ups between insulin products.

Women of Reproductive Potential

Advise patients to inform their health care professional if they are pregnant or are contemplating pregnancy.

Instruct patients on the management of hypoglycemia to use caution when driving or operating machinery.

Hypersensitivity Reactions

Advise patients that hypersensitivity reactions have occurred with FIASP®. Inform patients on the symptoms of hypersensitivity reactions [see Warnings and Precautions (5.6)].

Hypoglycemia due to Medication Errors

Instruct patients to always check the insulin label before each injection to avoid mix-ups between insulin products.

Women of Reproductive Potential

Advise patients to inform their health care professional if they are pregnant or are contemplating pregnancy.

Instruct patients on the management of hypoglycemia to use caution when driving or operating machinery.
Patient Information
FIASP® (fee’ asp)  
(insulin aspart injection)
for subcutaneous or intravenous use

Do not share your FIASP® with other people, even if the needle has been changed. You may give other people a serious infection, or get a serious infection from them.

What is FIASP®?
- FIASP® is a man-made insulin that is used to control high blood sugar in adults with diabetes mellitus.
- It is not known if FIASP® is safe and effective in children.

Who should not take FIASP®?
Do not take FIASP® if you:
- are having an episode of low blood sugar (hypoglycemia).
- have an allergy to insulin aspart or any of the ingredients in FIASP®.

Before taking FIASP®, tell your healthcare provider about all your medical conditions including, if you:
- have kidney problems.
- have liver problems.
- are pregnant or plan to become pregnant. Talk with your healthcare provider about the best way to control your blood sugar if you plan to become pregnant or while you are pregnant.
- are breastfeeding or plan to breastfeed. It is not known if FIASP® passes into your breast milk. Talk with your healthcare provider about the best way to feed your baby while using FIASP®.
- are taking new prescription or over-the-counter medicines, vitamins, or herbal supplements.

Before you start taking FIASP®, talk to your healthcare provider about low blood sugar and how to manage it.

How should I take FIASP®?
- Read the Instructions for Use that come with your FIASP®.
- Take FIASP® exactly as your healthcare provider tells you to.
- FIASP® starts acting fast. You should take your dose of FIASP® at the beginning of the meal or within 20 minutes after starting a meal.
- Know the type and strength of insulin you take. Do not change the type of insulin you take unless your healthcare provider tells you to. The amount of insulin and the best time for you to take your insulin may need to change if you take different types of insulin.
- If you miss a dose of FIASP®, monitor your blood sugar levels to decide if an insulin dose is needed. Continue with your regular dosing schedule at the next meal.
- Check your blood sugar levels. Ask your healthcare provider what your blood sugars should be and when you should check your blood sugar levels.
- Do not reuse or share needles with other people. You may give other people a serious infection or get a serious infection from them.

What should I avoid while taking FIASP®?
While taking FIASP® do not:
- Drive or operate heavy machinery until you know how FIASP® affects you.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol.

What are the possible side effects of FIASP®?
FIASP® may cause serious side effects that can lead to death, including:
- low blood sugar (hypoglycemia). Signs and symptoms that may indicate low blood sugar include:
  - dizziness or light-headedness
  - anxiety, irritability, or mood changes
  - slurred speech
  - confusion
  - headache
  - fast heart beat
Your insulin dose may need to change because of:
- change in level of physical activity or exercise
- change in diet
- weight gain or loss
- low potassium in your blood (hypokalemia).
- serious allergic reactions (whole body reactions). Get emergency medical help right away, if you have any of these signs or symptoms of a severe allergic reaction:
  - a rash over your whole body, trouble breathing, a fast heartbeat, swelling of your face, tongue or throat, swelling, extreme drowsiness, dizziness, confusion.
- heart failure. Taking certain diabetes pills called TZDs (thiazolidinediones) with FIASP® may cause heart failure in some people. This can happen even if you have never had heart failure or heart problems before. If you already have heart failure it may get worse while you take TZDs with FIASP®. Your healthcare provider should monitor you closely while you are taking TZDs with FIASP®. Tell your healthcare provider if you have any new or worse symptoms of heart failure including:
  - Shortness of breath, swelling of your ankles or feet, sudden weight gain.
Treatment with TZDs and FIASP® may need to be adjusted or stopped by your healthcare provider if you have new or worse heart failure.

Common side effects of FIASP® may include:
- skin problems such as eczema, rash, itching, redness and swelling of your skin (dermatitis)
- reactions at the injection site such as itching, rash
- skin thickening or pits at the injection site (lipodystrophy)
- weight gain
These are not all the possible side effects of FIASP®. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of FIASP®.
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your pharmacist or healthcare provider for information about FIASP® that is written for health professionals. Do not use FIASP® for a condition for which it was not prescribed. Do not give FIASP® to other people, even if they have the same symptoms that you have. It may harm them.

What are the ingredients in FIASP®?
Active Ingredient: insulin aspart
Inactive Ingredients: glycerol, phenol, metacresol, zinc, disodium phosphate dihydrate, arginine hydrochloride, niacinamide and water for injections

Manufactured by:
Novo Nordisk A/S
DK-2880 Bagsvaerd, Denmark
For more information, go to www.novonordisk-us.com or call 1-800-727-6500.

This Patient Information has been approved by the U.S. Food and Drug Administration.
Revised: 09/2017
Instructions for Use
FIASP® (flex' asp) FlexTouch® Pen
(insulin aspart injection)
• Do not share your FIASP® FlexTouch® Pen with other people, even if the needle is changed. You may give other people a serious infection, or get a serious infection from them.
• FIASP® FlexTouch® Pen (“Pen”) is a prefilled disposable pen containing 300 units of U-100 FIASP® (insulin aspart injection). You can inject from 1 to 80 units in a single injection. The units can be increased by 1 unit at a time.
• People who are blind or have vision problems should not use the Pen without help from a person trained to use the Pen.
• Do not use a syringe to remove FIASP® from the FlexTouch® Pen.
Supplies you will need to give your FIASP® injection:
• FIASP® FlexTouch® Pen
• a new NovoFine®, NovoFine® Plus or NovoTwist® needle
• alcohol swab
• a sharps container for throwing away used Pens and needles.
See “After your injection” at the end of these instructions.
Preparing your FIASP® FlexTouch® Pen:
• Wash your hands with soap and water.
• Before you start to prepare your injection, check the FIASP® FlexTouch® Pen label to make sure you are taking the right type of insulin. This is especially important if you take more than 1 type of insulin.
• FIASP® should look clear and colorless. Do not use FIASP® if it is thick, cloudy, or is colored.
• Do not use FIASP® past the expiration date printed on the label or 28 days after you start using the Pen.
• Always use a new needle for each injection to help ensure sterility and prevent blocked needles. Do not reuse or share needles with another person. You may give other people a serious infection, or get a serious infection from them.

NovoFine®

NovoFine® Plus

NovoTwist®

Priming your FIASP® FlexTouch® Pen:

Step 7:
• Turn the dose selector to select 2 units (See Figure H).

Step 8:
• Hold the Pen with the needle pointing up. Tap the top of the Pen gently a few times to let any air bubbles rise to the top (See Figure I).

Step 9:
• Hold the Pen with the needle pointing up. Press and hold in the dose button until the dose counter shows “0”. The “0” must line up with the dose pointer.
• A drop of insulin should be seen at the needle tip (See Figure J).
  o If you do not see a drop of insulin, repeat steps 7 to 9, no more than 6 times.
  o If you still do not see a drop of insulin, change the needle and repeat steps 7 to 9.

Selecting your dose:
Step 10:
Check to make sure the dose selector is set at 0.
• Turn the dose selector to select the number of units you need to inject. The dose pointer should line up with your dose (See Figure K).
  o If you select the wrong dose, you can turn the dose selector forwards or backwards to the correct dose.
  o The even numbers are printed on the dial.
  o The odd numbers are shown as lines.
• The FIASP® FlexTouch® Pen insulin scale will show you how much insulin is left in your Pen (See Figure L).
  o If the dose counter shows less than 80, the number shown in the dose counter is the number of units left in your Pen.
Giving your injection:

• Inject your FIASP® exactly as your healthcare provider has shown you. Your healthcare provider should tell you if you need to pinch the skin before injecting.

• You should take your dose of FIASP® at the start of a meal or within 20 minutes after starting a meal.

• FIASP® can be injected under the skin (subcutaneously) of your stomach area (abdomen), upper legs (thighs) or upper arms. Do not inject FIASP® into your muscle.

• Change (rotate) your injection sites within the area you choose for each dose. Do not use the same injection site for each injection.

Step 11:

• Choose your injection site and wipe the skin with an alcohol swab. Let the injection site dry before you inject your dose (See Figure M).

Step 12:

• Insert the needle into your skin (See Figure N).

  – Make sure you can see the dose counter. Do not cover it with your fingers; this can stop your injection.

  – Keep the needle in your skin after the dose counter has returned to “0” and slowly count to 6 (See Figure O).

    – The “0” must line up with the dose pointer. You may then hear or feel a click.

    – Do not recap the needle. Recapping the needle can lead to needle stick injury.

  – If you do not have a sharps container, carefully slip the needle into the outer needle cap (See Figure S). Safely remove the needle and throw it away as soon as you can.

    – Do not store the Pen with the needle attached. Storing without the needle attached helps prevent leaking, blocking of the needle, and air from entering the Pen.

Step 13:

• Press and hold down the dose button until the dose counter shows “0” (See Figure O).

  – If you see a stream of insulin coming from the needle tip, you may see a stream of insulin coming from the needle tip.

  – If you see a stream of insulin coming from the needle tip you will not get your full dose. If this happens you should check your blood sugar levels more often because you may need more insulin.

Step 14:

• Pull the needle out of your skin (See Figure Q).

  – If you see blood after you take the needle out of your skin, press the injection site lightly with a piece of gauze or an alcohol swab. Do not rub the area.

Step 15:

• Carefully remove the needle from the Pen and throw it away (See Figure R).

  – Do not recap the needle. Recapping the needle can lead to needle stick injury.

  – If you do not have a sharps container, carefully slip the needle into the outer needle cap (See Figure S). Safely remove the needle and throw it away as soon as you can.

    – Do not store the Pen with the needle attached. Storing without the needle attached helps prevent leaking, blocking of the needle, and air from entering the Pen.

Step 16:

• Replace the Pen cap by pushing it straight on (See Figure T).

After your injection:

• Put your used FIASP® FlexTouch® Pen and needles in a FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles and Pens in your household trash.

• 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

Additional information about the safe and effective use of FIASP®:

• Keep FIASP® FlexTouch® Pens and needles out of the reach of children.

• Always use a new needle for each injection.

• Do not share FIASP® FlexTouch® Pens or needles with other people. You may give other people a serious infection, or get a serious infection from them.

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

**FIASP® (fee’ asp)**
(insulin aspart injection)
10 mL vial (100 units/mL, U-100)

Read these Instructions for Use before you start taking FIASP® and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment. The vial is not recommended for use by the blind or visually impaired without the assistance of a person trained in the proper use of the product and insulin syringe.

Do not reuse or share syringes or needles with other people. You may give other people a serious infection or get a serious infection from them.

**Supplies you will need to give your FIASP® injection:**
- a 10 mL FIASP® vial
- a U-100 insulin syringe and needle
- 2 alcohol swabs
- 1 sharps container for throwing away used needles and syringes. See “Disposing of your used needles and syringes” at the end of these instructions.

**Preparing your FIASP® dose:**
- **Do not** roll or shake the FIASP® vial. Shaking the FIASP® vial right before the dose is drawn into the syringe may cause bubbles or foam. This can cause you to draw up the wrong dose of insulin.
- The tamper-resistant cap should not be loose or damaged before the first use. **Do not** use if the tamper-resistant cap is loose or damaged before using FIASP® for the first time.
- Wash your hands with soap and water.
- **Before you start to prepare your injection**, check the FIASP® label to make sure that you are taking the right type of insulin. This is especially important if you use more than 1 type of insulin.
  - Check that the FIASP® vial is not cracked or damaged.
  - **Do not** use if the FIASP® vial is cracked or damaged.
  - FIASP® should look clear and colorless. **Do not** use FIASP® if it is thick, cloudy, or is colored.
  - **Do not** use FIASP® past the expiration date printed on the label.

**Steps:**

1. **Step 1:** Pull off the tamper-resistant cap (See Figure A).
2. **Step 2:** Wipe the rubber stopper with an alcohol swab (See Figure B).
3. **Step 3:** Hold the syringe with the needle pointing up. Pull down on the plunger until the tip of the plunger reaches the line for the number of units for your prescribed dose (See Figure C).
4. **Step 4:** Push the needle through the rubber stopper of the FIASP® vial (See Figure D).
5. **Step 5:** Push the plunger all the way in. This puts air into the FIASP® vial (See Figure E).
6. **Step 6:** Turn the FIASP® vial and syringe upside down and slowly pull the plunger down until the tip of the plunger is a few units past the line for your dose (See Figure F).
7. **Step 7:** Slowly push the plunger up until the tip of the plunger reaches the line for your prescribed FIASP® dose (See Figure H).
8. **Step 8:** Check the syringe to make sure you have the right dose of FIASP®.
9. **Step 9:** Pull the syringe out of the rubber stopper on the vial (See Figure I).
10. **Step 10:** Choose your injection site and wipe the skin with an alcohol swab (See Figure J). Let the injection site dry before you inject your dose.
11. **Step 11:** Insert the needle into your skin. Push down on the plunger to inject your dose (See Figure K). Make sure you have injected all the insulin in the syringe.
12. **Step 12:** Pull the needle out of your skin. After your injection you may see a drop of FIASP® at the needle tip. This is normal and does not affect the dose you just received (See Figure L).
   - If you see blood after you take the needle out of your skin, press the injection site lightly with a piece of gauze or an alcohol swab. **Do not** rub the area.

After your injection:
- **Do not** recap the needle. Recapping the needle can lead to needle stick injury.

**Disposing of your used needles and syringes:**
Put your used insulin needles and syringes in a FDA-cleared sharps disposal container right after use. Do not throw away (dispose of) loose needles and syringes in your household trash.
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, and
- 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. Do not reuse or share needles or syringes with another person. For more information about 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.

**How should I store FIASP®?**
- **Do not** freeze FIASP®. **Do not** use FIASP® if it has been frozen.
- Keep FIASP® away from excessive heat or light.
- Store unopened FIASP® vials in the refrigerator at 36°F to 46°F (2°C to 8°C) or at room temperature below 86°F (30°C).
- Store opened FIASP® vials in the refrigerator at 36°F to 46°F (2°C to 8°C) or at room temperature below 86°F (30°C).
- Unopened FIASP® vials may be used until the expiration date printed on the label, if they are kept in the refrigerator.
- **If FIASP® vials are stored at room temperature prior to first use, they should be used or thrown away within 28 days.**
- **Opened FIASP® vials should be thrown away after 28 days,** even if they still have insulin left in them.

**Giving your FIASP® injection:**
- Inject your FIASP® exactly as your healthcare provider has shown you. Your healthcare provider should tell you if you need to pinch the skin before injecting.
- You should take your dose of FIASP® at the start of a meal or within 20 minutes after starting a meal.
- FIASP® can be injected under the skin (subcutaneously) of your stomach area, upper legs, or upper arms. **Do not** inject FIASP® into your muscle.
- Change (rotate) your injection site for each injection. **Do not** use the same injection site for each injection.
- **Do not** dilute or mix FIASP® with any other type of insulin products or solutions.
General information about the safe and effective use of FIASP®

• Always use a new syringe and needle for each injection to help ensure sterility and prevent blocked needles.
• Do not reuse or share syringes or needles with other people. You may give other people a serious infection or get a serious infection from them.
• Keep FIASP® vials, syringes, and needles out of the reach of children.

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

**FIASP® (fee’asp) PenFill® 3 mL cartridge 100 Units/mL (U-100) (insulin aspart injection)**

- Do not share your PenFill® cartridge or PenFill® cartridge compatible insulin delivery device with other people, even if the needle has been changed. You may give other people a serious infection, or get a serious infection from them.
- Your healthcare provider should show you or your caregiver how to inject FIASP® the right way before you inject it for the first time.

**FIASP® PenFill® cartridge 100 Units/mL is a prefilled cartridge containing 300 units of U-100 FIASP® (insulin aspart injection).**

- After you insert the PenFill® cartridge in your device, you can use it for multiple injections. Read the instruction manual that comes with your insulin delivery device for complete instructions on how to use the PenFill® cartridge with the device.
- This PenFill® cartridge is not recommended for use by the blind or visually impaired without the assistance of a person trained in the proper use of the product and your insulin delivery device.
- If using a new FIASP® PenFill® cartridge, start with Step 1.
- If the FIASP® PenFill® cartridge has already been used, start with Step 2.

**Supplies you will need to give your FIASP® injection:**

- **FIASP® PenFill® cartridge**
- Novo Nordisk 3 mL PenFill® cartridge compatible insulin delivery device
- 1 new NovoFine®, NovoFine® Plus, or NovoTwist® needle
- Alcohol swab
- Adhesive bandage
- Cotton gauze
- A sharps container for throwing away unused PenFill® cartridges and needles. See “After your injection” at the end of these instructions.

**FIASP® cartridge compatible insulin delivery device**

**NovoFine®**

- Outer needle cap
- Inner needle cap
- Needle
- Paper tab

**NovoFine® Plus**

- Outer needle cap
- Inner needle cap
- Needle
- Paper tab

**NovoTwist®**

- Outer needle cap
- Inner needle cap
- Needle
- Paper tab

**PenFill® cartridge compatible insulin delivery device**

**PenFill® cartridge 3 mL (example)**

### How to use the FIASP® PenFill® cartridge

1. Wash your hands with soap and water.
2. Before you start to inject your FIASP® PenFill® cartridge label to make sure that it contains the insulin you need. This is especially important if you take more than 1 type of insulin.
3. The tamper-resistant foil should be in place before the first use. If the foil has been broken or removed before your first use of the cartridge, do not use it. Call Novo Nordisk at 1-800-727-6500.
4. Carefully look at the cartridge and the inside. Check that the FIASP® cartridge:
   - Is not damaged, for example cracked or leaking
   - Is not loose on the threaded end
   - Should look clear and colorless. Do not use FIASP® if it is cloudy or colored or if the threaded end is loose (See Figure B).

#### Step 1:

- Insert a 3 mL cartridge with the threaded end first into your Novo Nordisk 3 mL PenFill® cartridge compatible insulin delivery device (See Figure C).
- If you drop your device, check the insulin cartridge for damage such as cracks or leaking. If your cartridge is damaged, throw it away and use a new one.

#### Step 2:

- Take a new needle, and tear off the paper tab. Always use a new needle for each injection to make sure the needle is free of germs (sterile) and to prevent blocked needles. Do not attach a new needle to your device until you are ready to give your injection. Do not reuse or share your needles with other people. You may give others a serious infection, or get a serious infection from them.
- Be careful not to bend or damage the needle before you use it.
- Push the needle straight onto the device. Turn the needle clockwise until it is on tight (See Figure D).

#### Step 3:

- Pull off the outer needle cap (See Figure E). Do not throw it away. You will need it after the injection to safely remove the needle.
- For each injection, change (rotate) your injection site within the area of skin that you use. Do not use the same injection site for each injection.
- Clean your injection site with an alcohol swab. Let your skin dry. Do not touch this area again before injecting.
- Insert the needle into your skin. Press and hold down the dose button until the dose counter shows “0”. Continue to keep the dose button pressed and keep the needle in your skin and slowly count to 6 (see Figure J).
- Remove the needle from your skin.

#### Step 4:

- Pull off the inner needle cap and throw it away (See Figure F). Do not try to put the inner needle cap back on the needle.

#### Step 5:

- Small amounts of air may collect in the cartridge during normal use. You must do an airshot before each injection to avoid injecting air and to make sure you receive the prescribed dose of your medicine.
- Do the airshot as described in the instruction manual that comes with your device.
- Keep testing your Novo Nordisk 3 mL PenFill® cartridge compatible insulin delivery device until you see insulin at the needle tip. If you still do not see a drop of insulin after 6 times, change the needle and repeat this step. This makes sure that any air bubbles are removed and that insulin is getting through the needle (See Figure G).

#### Select your dose

- Check to make sure that the dose counter is set to 0.
- Turn the dose selector clockwise to select the dose you need to inject (See Figure H). The pointer should line up with your dose. When turning the dose selector, be careful not to press the dose button as insulin will come out. You will hear a click for every single unit dialed. Do not set the dose by counting the number of clicks you hear because you may get an incorrect dose.
- Refer to your insulin delivery device manual if necessary.

### Inject your dose

- Do the injection exactly as shown to you by your healthcare provider. Your healthcare provider should tell you if you need to pinch the skin before injecting.
- You should take your dose of FIASP® at the start of a meal or within 20 minutes after starting a meal.
- **FIASP® can be injected under the skin (subcutaneously) of your stomach area (abdomen), upper legs (thighs), or upper arms (See Figure I).**
- For each injection, change (rotate) your injection site within the area of skin that you use. Do not use the same injection site for each injection.
- Clean your injection site with an alcohol swab. Let your skin dry. Do not touch this area again before injecting.
- Insert the needle into your skin. Press and hold down the dose button until the dose counter shows “0”. Continue to keep the dose button pressed and keep the needle in your skin and slowly count to 6 (see Figure J).
- Remove the needle from your skin.
You may see a drop of FIASP® at the needle tip after injecting. This is normal and has no effect on the dose you just received. If blood appears after you take the needle out of your skin, press the injection site lightly with a cotton gauze and cover with an adhesive bandage, if necessary. Do not rub the area.

After your injection

Step 8:
- Lay your outer needle cap on a flat surface. Carefully, lead the needle tip into the outer needle cap without touching the needle (See Figure K) and push the outer needle cap completely on.
- Hold the black cartridge holder on the insulin delivery device and unscrew the needle counterclockwise (See Figure L).
- Throw away (dispose of) the needle in an FDA-cleared sharps container as your healthcare professional has instructed you.
- Put your empty FIASP® PenFill® cartridge and used needles in a FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles and PenFill® cartridges in your household trash.
- 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. Do not reuse or share your needles or syringes with other people. 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.

Step 9:
- Keep the 3 mL PenFill® cartridge in the device. Do not store your device with a needle attached. This will prevent infection or leakage of insulin and will make sure that you receive the right dose of FIASP®.
- Put the pen cap on your device after each use to protect the insulin from light (See Figure M).

How should I store my FIASP® PenFill® cartridge?

Before use:
- Store unused FIASP® PenFill® cartridges in the refrigerator at 36°F to 46°F (2°C to 8°C).
- Do not freeze FIASP®. Do not use FIASP® if it has been frozen.
- Unused PenFill® cartridges may be used until the expiration date printed on the label, if kept in the refrigerator.
- If FIASP® is stored mistakenly outside of refrigeration between 47°F (9°C) to 86°F (30°C) prior to first use, it should be used within 28 days or thrown away.

PenFill® cartridges in use:
- Store the PenFill® cartridge you are currently using in the insulin delivery device at room temperature below 86°F (30°C) for up to 28 days. Do not refrigerate.
- Keep FIASP® away from heat or light.
- The FIASP® PenFill® cartridge you are using should be thrown away after 28 days, even if it still has insulin left in it.

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

Manufactured by:
Novo Nordisk A/S
DK-2880 Bagsvaerd, Denmark

Revised: 09/2018
© 2018 Novo Nordisk
US18FSP00169 October 2018