

## press release

### **Novo Nordisk Receives FDA Approval for Fiasp®, a New Fast-Acting Mealtime Insulin**

**Plainsboro, N.J. (September 29, 2017)** – Novo Nordisk today announced that the U.S. Food and Drug Administration (FDA) approved Fiasp® (insulin aspart injection) 100 Units/mL, a fast-acting mealtime insulin indicated to improve glycemic control in adults with type 1 and type 2 diabetes.<sup>1</sup> Fiasp® can be dosed at the beginning of a meal or within 20 minutes after starting a meal. Fiasp® is a new formulation of NovoLog®, in which the addition of niacinamide (vitamin B3) helps to increase the speed of the initial insulin absorption, resulting in an onset of appearance in the blood in approximately 2.5 minutes.<sup>2</sup> Fiasp® will be available in a pre-filled delivery device FlexTouch® pen and a 10 mL vial.<sup>1</sup>

Many adults with type 1 and type 2 diabetes struggle with blood sugar control after meals. The result of this has led to many people with diabetes not achieving their target A1C.

“With Fiasp®, we’ve built on the insulin aspart molecule to create a new treatment option to help patients meet their post-meal blood sugar target,” said Bruce Bode, MD FACE, President of Atlanta Diabetes Associates and Associate Professor at Emory University School of Medicine. “The intention of rapid acting insulin therapy is to mimic, as much as possible, the natural physiological insulin response that occurs after meals, a process that is important for optimal A1C management.”

Fiasp® will launch at the same list price as NovoLog® and will be offered with a Savings Card program for eligible patients with commercial insurance to reduce co-pays. Fiasp® will also be available to eligible patients through the Novo Nordisk Patient Assistance Program. Patients and caregivers can obtain more information and access to the Novo Nordisk Patient Assistance Program by calling toll free at 866-310-7549.

The approval of Fiasp® is based on results from the onset phase 3a clinical development program. The clinical trials enrolled more than 2,000 adults with type 1 and type 2 diabetes to evaluate the efficacy and safety of Fiasp® administered both at mealtime and after starting a meal. Data from the trials showed that Fiasp® demonstrated a reduction in A1C in adults with type 1 and type 2 diabetes.<sup>1</sup> Common adverse reactions, excluding

hypoglycemia, occurring in  $\geq 5\%$  of subjects included nasopharyngitis, upper respiratory tract infection, nausea, diarrhea and back pain.<sup>1</sup>

### **Patient Information**

#### **FIASP® (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
  - sweating
  - confusion
  - headache
  - blurred vision
  - slurred speech
  - shakiness
  - fast heart beat
  - anxiety, irritability, or mood changes
  - hunger

#### Your insulin dose may need to change because of:

- change in level of physical activity or exercise
- 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, sweating, 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



- Centers for Disease Control and Prevention. Long-term trends in diabetes. CDC website. [https://www.cdc.gov/diabetes/statistics/slides/long\\_term\\_trends.pdf](https://www.cdc.gov/diabetes/statistics/slides/long_term_trends.pdf). Accessed September 2017.

Fiasp<sup>®</sup>, NovoLog<sup>®</sup> and FlexTouch<sup>®</sup> are registered trademarks of Novo Nordisk A/S.

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