

## Special Interest Articles:

- Fiasp
- Kratom
- Opioid Crisis



## Did you know?

During 2013-14, the CDC received 42 reports of disease outbreaks in the United States related to drinking water. Of those reported, 57% of them were linked to *Legionella*. The outbreaks accounted for 1006 cases, which resulted in 13 deaths. Outbreak settings included hospitals, long-term care facilities, camps, hotels, and apartment buildings.

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## Fiasp® - New Formulation of Insulin Aspart Injection Kennedy Smith, Samford University PharmD Candidate, 2018

Fiasp® (insulin aspart injection) is a rapid-acting insulin analog for subcutaneous or intravenous administration used to lower blood glucose. Insulin aspart is similar to regular human insulin with a single substitution of the amino acid proline by aspartic acid in position B28. Fiasp is indicated to improve glycemic control in adults with type 1 and type 2 diabetes mellitus. Fiasp is available as a 10 mL multiple-dose vial and a 3 mL single-patient-use FlexTouch pen. It is to be given at the start of a meal or within 20 minutes of starting a meal, into the abdomen, upper arm, or thigh.

Compared to Novolog®, Fiasp contains two additional excipients: nicotinamide (also known as niacinamide or vitamin B3) and L-arginine hydrochloride (an amino acid). Nicotinamide is intended to result in a faster initial absorption of insulin aspart following subcutaneous injection, and L-arginine hydrochloride is intended to help stabilize the Fiasp formulation. The insulin aspart molecule in Fiasp is identical to Novolog; therefore, once systemically absorbed, it has the same biological action at the insulin receptor. In a 26-week randomized, double-blind study with 689 patients with Type 2 diabetes, patients were randomized to either mealtime Fiasp or to mealtime NovoLog, both in combination with insulin glargine and metformin in a basal- bolus regimen, where the treatment difference in HbA1c reduction from baseline between the two treatments met the pre-specified non-inferiority margin(0.4%).

In another 26-week randomized study with 1143 patients with Type 1 diabetes, patients were randomized to blinded mealtime Fiasp, blinded mealtime NovoLog, or open-label post-meal Fiasp, all in combination with once or twice daily insulin detemir. The treatment difference in HbA1c reduction from baseline between mealtime Fiasp compared to mealtime NovoLog, and the treatment difference between post-meal Fiasp compared to mealtime NovoLog met the pre-specified non-inferiority margin.

Adverse reactions observed with Fiasp include hypoglycemia, allergic reactions, hypersensitivity, injection site reactions, lipodystrophy, weight gain, nasopharyngitis, upper respiratory tract infection, nausea, diarrhea, and back pain.

No safety issues have been identified for nicotinamide or L-arginine even with daily exposure of dose sufficient for highly insulin-resistant patients.



## References

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2. Assessment Report: Fiasp [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/EPAR\\_-\\_Public\\_assessment\\_report/human/004046/WC500220940.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Public_assessment_report/human/004046/WC500220940.pdf). Published November 10, 2016. (Accessed November 7, 2017).



## Opioid Crisis Update

**Sarah Wright, Samford University PharmD Candidate 2018**

On November 1, 2017, the President's Commission on Combating Drug Addiction and the Opioid Crisis released its final report. The report's recommendations, of which there were 56, include expanded access to medication assisted treatment, improved prevention programs, and identification of guidelines that can be improved. The report calls for pharmacists to be trained on best practices to evaluate the validity of opioid prescriptions and to not be punished for rejecting inappropriate prescriptions. Over 52,000 deaths were caused by drug overdose in 2015. According to the CDC, deaths by drug overdose increased by more than 20% from 2015 to 2016.

The current opioid epidemic is not just affecting adults. Researchers from the Yale School of Medicine have found that the number of children who were treated in an emergency setting for a unintentional to intentional drug overdose had more than doubled between 1997 and 2012. The greatest increase was among the 1 to 4 years-of-age group. Between 1997 and 2012, a total of 13,052 hospitalizations due to prescription opioid overdoses were identified for ages 1-19 years. The annual incidence of overdose hospitalization per 100,000 children rose from 1.4 to 3.71, or by 165 percent. Even in children younger than 6 years old, opioids now account for most of the drug poisonings in this group, followed by benzodiazepines. Most of the time, the child was inadvertently exposed to a prescription intended for an adult in the household. The incidence of unintentional poisonings increased by 82 percent from 0.17 in 1997 to 0.31 in 2012. "In teens ages 15 to 19, opioid poisonings attributed to suicide or self-inflicted injury increased by 140 percent, while those attributed to accidental intent increased 303 percent," the team said. A pattern of methadone abuse has also been observed, with hospitalizations increasing almost 10-fold among 15-19 year olds from 1997 to 2012. Research suggests that overdoses by prescription and illicit opioids are likely to remain a persistent, growing problem in children and adolescents unless greater attention is directed toward the pediatric community, who make up nearly a fourth of the U.S. population.

The removal of these drugs from the home is critical. On a local level, the DEA's fourteenth semi-annual Prescription Drug Take-Back Day on October 28, 2017 saw Alabama collect more than 7,000 pounds of prescription drugs for disposal at its many collection sites across the state. A record-setting 912,305 pounds were collected from across the country. The next Prescription Drug Take-Back Day is set for April 28, 2018.



### References

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4. Gaither JR, Leventhal JM, Ryan SA, Camenga DR. National trends in hospitalizations for opioid poisonings among children and adolescents, 1997 to 2012. *JAMA Pediatr*. 2016;170(12):1195-1201. doi:10.1001/jamapediatrics.2016.2154. October 31, 2016. (Accessed November 9, 2017).
5. Drug Enforcement Administration collects record number of unused pills as part of its 14<sup>th</sup> Prescription Drug Take-Back Day. The United States Attorney's Office. United States Department of Justice website. <https://www.justice.gov/usao-ndal/pr/drug-enforcement-administration-collects-record-number-unused-pills-part-its-14th>. (Accessed November 9, 2017).