PULSE

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Pharmacy Benefit Dimensions®

Feb. 1, 2020 Volume 2 | Issue 3

Clinical Updates

FDA approves rapid-acting insulin for pediatric patients with diabetes

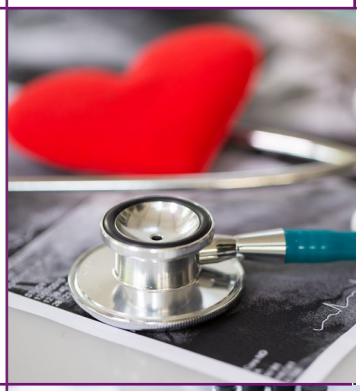
On Jan. 6, 2020, Novo Nordisk announced the U.S. Food and Drug Administration (FDA) approved the expanded use of Fiasp® (insulin aspart) to include children. Fiasp® is a rapid-acting mealtime insulin injection approved for use in adult diabetic patients in 2017. Fiasp® was approved for use in children based on the onset® 7 clinical trial, that showed Fiasp® was safe and effective in pediatric and adolescent patients with type 1 diabetes when compared to conventional insulin aspart therapy. Fiasp® is the only rapid-acting insulin for which pre-meal dosing is not required. Instead, Fiasp® can be administered at the beginning of a meal or within 20 minutes of starting a meal, which offers flexibility for patients managing their diabetes. The Centers for Disease Control and Prevention (CDC) estimates that about 193,000 Americans under age 20 are diagnosed with diabetes.

Safety First

Mylan issues voluntary nationwide recall of heartburn medication

On Jan. 8, 2020, Mylan Inc. announced a consumer-level voluntary recall of three lots of nizatidine capsules, a medication commonly used to treat ulcers in the digestive tract and heartburn due to gastric reflux. The recall has been issued due to the detection of low levels of an impurity, known as N-nitrosodimethylamine (NDMA), which is classified as a probable cancer-causing substance by the International Agency for Research on Cancer (IARC). Mylan is notifying its distributors and customers and is arranging for the return of all recalled products. While Mylan has not received any reports of adverse events related to these batches, the FDA advises consumers to contact their health care provider if they have experienced any problems that could be related to this medication.

From the Industry



FDA grants AstraZeneca's Farxiga® Priority Review for heart failure indication

On Jan. 6, 2020, AstraZeneca announced that the FDA granted Priority Review for its application to expand the use of their diabetic medication, Farxiga® (dapagliflozin). Farxiga® is currently approved to treat diabetes and reduce the risk of hospitalization for heart failure in diabetic patients. The application under review with the FDA is for an expanded use of Farxiga® to include reducing the risk of heart-related (cardiovascular) death or worsening heart failure in adult patients with or without diabetes. Priority Review designation ensures the agency will decide on the application within six months – significantly faster than the standard review period of 10 months. Farxiga® is a well-established treatment for type 2 diabetes, but the approval of this additional indication would make it the first and only medication in its class to treat patients with heart failure.

Recent FDA Approvals

Novel Drug Approval: Ayvakit™ (avapritinib)
Oral tablet for the treatment of adult patients with a gastric tumor, known as gastrointestinal stromal tumor (GIST) [1/9/2020 – Orphan Drug; Priority Review – BLUEPRINT MEDICINES CORP]

New Dosage Form: Valtoco® (diazepam)
Nasal spray for the treatment of episodes of seizure activity that are distinct from usual seizure patterns in patients aged 6 years and older [1/10/2020 – Orphan Drug – NEURELIS INC]

New Formulation: Monoferric™ (ferric derisomaltose)
Intravenous injection for the treatment of iron deficiency anemia in adult patients who have failed oral iron supplements or have chronic kidney disease [1/16/2020 – PHARMACOSMOS AS]

New Generics Entering the Marketplace

Silenor® (doxepin)
Indication: Insomnia
Dosage Form/Strength: 3MG, 6MG Tablet
Average Wholesale Price (AWP): Generic = $266 | Brand = $599

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