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Aimovig™: First FDA Approved Anti-GGRP for Migraine Therapy

By Frankie Kaldi, Samford University PharmD Candidate 2019

Migraine headaches can cause those affected by them to lose more than half of their lives to *migraine days*. Migraines can take away time with family, productivity at home and work, and livelihood in general. Migraines cause severe throbbing pain and/or a pulsing sensation, normally on just one side of the head. They usually progress to nausea, vomiting, and sensitivity to light and sound.

Aimovig (erenumab-aooe) is the first FDA approved medication that is specifically designed to prevent migraines by blocking the calcitonin gene-related peptide (CGRP) receptor. CGRP binds to this receptor and plays a key role in migraine. Aimovig binds to this receptor and prevents CGRP binding, therefore preventing many migraines from occurring.

Aimovig is given once-monthly by subcutaneous self-injection. Usual dosing is 70 mg (one pen), however some patients may benefit from 140 mg (two pens) still given once monthly as two consecutive 70 mg injections. In a recent study, 246 patients were randomized to either Aimovig 140 mg monthly or placebo for 12 weeks. Patients receiving Aimovig had three-fold higher odds of their *migraine days* being cut by at least 50% as compared to placebo. Patients also experienced a decrease in monthly acute migraine-specific drug use.

Most common adverse effects include constipation (3% of patients) and injection site reaction (5-6% of patients,) however, in studies there have been no adverse events leading to discontinuation of treatment in Aimovig groups. There are no contraindications to therapy listed in the manufacturer's labeling and no latex warning on the label concerning product packaging. The only drug known to have an interaction with Aimovig currently is belimumab, which could have its toxic effects increased when used alongside Aimovig. To date there are currently no reports of human or pediatric toxicity from overdose. (References on page 3)

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Special Interest Articles

- Aimovig
- Xofluza
- Jornay PM

Did you know?

Virginia-based company Kaleo, makers of the naloxone kit Evzio, raised the price by more than 600 percent between 2014 and 2017. A Senate subcommittee issued a report detailing this increase. The company responded by announcing it will release a generic version by midyear and will drop the brand name price in the coming 18 to 24 months.

Xofluza™: The First New FDA Approved Flu Drug in Nearly Two Decades

By Haiyen Chen, Samford University PharmD Candidate 2019

"Unlike the other currently available agents, Xofluza is a single-dose treatment course, which makes it appealing."

Influenza (flu) is a contagious respiratory illness caused by influenza viruses. It can cause mild to severe illness. Serious outcomes of flu infection can result in hospitalization or death. Some people, such as elderly, young children, and people with certain health conditions, are at high risk of serious flu complications. While flu vaccination is the best way to prevent seasonal flu, antiviral drugs are a second line of defense to treat.

In October of this year, the FDA approved Xofluza (baloxavir marboxil), just before the start of influenza season. Compared with current available influenza antivirals, neuraminidase inhibitors, Xofluza has a new antiviral mechanism. It inhibits the endonuclease activity of polymerase acidic (PA) protein, an influenza virus-specific enzyme in the viral RNA polymerase complex. By blocking the PA protein, Xofluza prevents viral gene transcription and ultimately influenza virus replication. As a result, it has shown efficacy in influenza strains resistant to neuraminidase inhibitors.

Xofluza is approved to treat acute uncomplicated influenza in patients 12 years of age and older who have been symptomatic for no more than 48 hours. Unlike the other currently available agents, Xofluza is a single-dose treatment course, which makes it appealing. Depending on the weight of patient, a single dose of 40 or 80 mg is recommended. Xofluza should not be taken with dairy products, calcium-fortified beverages, polyvalent cation-containing laxatives, antacids, or oral supplements (e.g., calcium, iron, magnesium, selenium, or zinc) per prescribing information.

Xofluza appears to be well tolerated. The most common adverse events are headache, GI upset (diarrhea, nausea, vomiting), bronchitis, nasopharyngitis, sinusitis, and increases in ALT level. No adverse effect was significantly more common with Xofluza compared to placebo or oseltamivir and only diarrhea and nausea were considered to be medication related.

There have been no reports of Xofluza overdoses. Treatment of an overdose of Xofluza should consist of general supportive measures including monitoring of vital signs and observation of the clinical status of the patient. There is no specific antidote for overdose with Xofluza and it is unlikely to be significantly removed by dialysis due to high serum protein binding.

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Jornay PM™: ADHD Nighttime Dosing Option

By Laura Read RPh, CSPI, Regional Poison Control Center

Parents and caregivers of children with attention-deficit/hyperactivity disorder (ADHD) whose symptoms can be severe during the early morning routine have a new treatment option. "Many parents of children with ADHD note that the early morning routine is often one of the most chaotic times of the day," said Randy Sallee, MD, PhD, chief medical officer at Ironshore, manufacturer of the new drug, Jornay PM. The medication is the first stimulant to be dosed in the evening and has been approved by the US Food and Drug Administration for the treatment of ADHD in patients aged 6 and older. It is expected to be on the market in the first half of 2019.

Jornay PM is a novel, extended-release formulation of methylphenidate. The medication's drug release technology contains two functional film coatings, one that delays the initial release of drug for up to 10 hours and a second layer to help control the rate of release of the active pharmaceutical ingredient throughout the day. The medication should be taken at 8 pm, but dosing can be taken any time between 6:30 pm and 9:30 pm to enhance tolerability and efficacy. Jornay PM will be available in 20, 40, 60, 80, and 100 mg capsules.

Common adverse reactions are decreased appetite, insomnia, nausea, vomiting, dyspepsia, abdominal pain, weight loss, anxiety, dizziness, irritability, tachycardia, and increases in blood pressure. In children specifically taking Jornay PM, headache, psychomotor hyperactivity, and mood swings were also seen.

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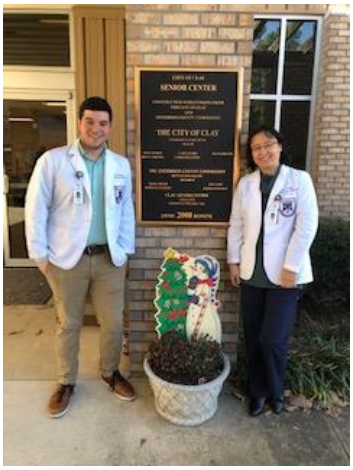

Frankie Kaldi and Haiyen Chen, pharmacy students from Samford University, gave a Medication Safety Talk to seniors in December at Clay Senior Citizen Center.