September 2016
Issue 17

RPCC Pharmacy Forum

Special Interest Articles:

- Aripiprazole
- EMSAM
- Aspirin-Containing Antacids

Did you know?

In 1951, the famous baby-faced character, Speedy Alka-Seltzer was born, featuring an Alka-Seltzer tablet body with hat and effervescent wand. In 1964, the original six-inch-high doll was insured for $100,000 and kept in a vault of a Beverly Hills bank.

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Aripiprazole- New FDA Warning

Mary Kate Pummer, Pharm. D. Candidate, 2017

Aripiprazole (Abilify®, Abilify Maintena®, Aristada®), is a second generation or atypical antipsychotic,that is FDA approved for use in adults and children as young as 6 years old, to treat bipolar disorder, schizophrenia, Tourette disorder, major depressive disorder, irritability associated with autism, and off-label for depression with psychotic features and psychosis related to Alzheimer's and other dementias. It was approved in November 2002, and became available as a generic product in April 2015. Aripiprazole is a dopamine partial agonist and a serotonin partial agonist ($5\text{-}HT_{1A}$)-antagonist ($5\text{-}HT_{2A}$). Most commonly, aripiprazole is used in the treatment of depression as an adjunct therapy when antidepressants give an inadequate response.

In the current package insert, there is a warning concerning compulsive gambling associated with use of aripiprazole and that dose reduction or discontinuation should be considered.

However, on May 3, 2016, the FDA released a new safety alert for this medication. Their statement listed that the drug labeling doesn't fully reflect the risk of impulse control problems that this drug may cause. These impulse control issues can happen to anyone who takes this medication and it could put patients or others in harm's way.

Compulsive or uncontrollable urges that have been reported with the use of this drug are urges to gamble, have sex, binge eat, and shop. These urges stop with the discontinuation of the medication in case reports.

The FDA is now requiring the additional warnings about these compulsions that may occur with the use of the drug to the product labeling and Medication Guide.

Healthcare professionals should be aware of this potential side effect with the use of aripiprazole and should make their patients aware of the potential to experience these compulsions or urges. It is also important to have your patients tell you if they begin to experience any new uncontrollable urges and to monitor them closely. It is also important to monitor patients with a family history of compulsion disorders, including obsessive-compulsive disorder, impulse-control disorder, bipolar disorder (particularly mania), alcoholism, substance abuse, and other addictions, which may make these patients higher risk of developing these urges.

The recommendation if patients develop new uncontrolled impulses is to reduce the dose or discontinue the medication and continue to monitor the patients.

For the full safety announcement, visit http://www.fda.gov/Drugs/DrugSafety/ucm

References

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2. U.S. Food and Drug Administration. Aripiprazole (Abilify, Abilify Maintena, Aristada): Drug Safety Communication. http://www.fda.gov/safety/medwatch/safetyinformation/safetyalertsforhumanmedicalproducts/ucm498823.htm. Published May 3, 2016. (Accessed September 1, 2016).

EMSAM- Transdermal Patch to Treat Major Depressive Disorder

Amanda Halstead, Pharm. D. Candidate, 2017

EMSAM (selegiline) is a transdermal patch that received FDA approval in 2006 to treat major depressive disorder, but it has been underutilized by practitioners. The lack of use has reportedly been due to possible severe adverse effects, high costs, and lack of comparative data. Selegiline is an irreversible monoamine oxidase inhibitor (MAO-I) of both MOA-A and MOA-B.Treatment guidelines for MAO-I toxicity have been established.

"Transdermal dosing results in substantially higher exposure to selegiline and lower exposure to metabolites compared to oral dosing, where extensive first-pass metabolism occurs.[2]"

The EMSAM patch is available in three strengths: 6 mg/24hr, 9 mg/24hr, and 12 mg/24hr. The half-life of the transdermal patch is eighteen to twenty-five hours. 25-30% of the patch content is absorbed over 24 hours, but drug absorption might be 33% higher than the average amount per twenty-four hours. Transdermal dosing results in substantially higher exposure to selegiline and lower exposure to metabolites compared to oral dosing, where extensive first-pass metabolism occurs.[2] Distribution is rapid.

All patients using the patch should be monitored for worsening depression, thoughts of suicide, attempts to commit suicide, and unusual changes in mood or behavior. The common adverse effects of EMSAM include application site reactions, xerostomia, orthostatic hypotension, headache, and gastrointestinal upset. Possible serious adverse effects include tyramine-induced hypertensive crisis, activation of mania/hypomania, and serotonin syndrome.

The 6 mg/24 hr patch does not require a special diet, but in overdose or high therapeutic dose regimens, patients should avoid tyramine containing foods like aged cheeses and meats, smoked fish, alcoholic beverages, yogurt, and soy products. EMSAM use is contraindicated with certain medications, including selective serotonin reuptake inhibitors, serotonin-norepinephrine reuptake inhibitors, tricyclic antidepressants, tramadol, carbamazepine, St. John's Wort, and cough medications containing dextromethorphan. Patients should not take EMSAM with or within two weeks of stopping contraindicated medications (5 weeks for fluoxetine); patients should wait two weeks after stopping EMSAM before they start contraindicated medications.

EMSAM patch use is contraindicated in any patients younger than age twelve, due to increased hypotension risk, and in patients with pheochromocytoma. It is pregnancy category C and should be discontinued during lactation. EMSAM patches should be disposed of properly. The patches should be folded in half, sticky sides together, and promptly thrown away into a container with a closed lid. EMSAM patches should always be kept out of reach of children and pets.

References

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2. EMSAM ® [package insert]. Morgantown, WV: Somerset Pharmaceuticals, Inc.; 2015.https://www.emsam.com/en/prescribing-information. (Accessed September 7, 2016).
3. Selegiline. Micromedex® 2.0, (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com. (Accessed August 31, 2016).
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FDA Issues Reminder- Aspirin-Containing Antacids Can Cause Bleeding

Launched in 1931, Alka-Seltzer® remains one of the most well-known over-the-counter products in the United States. Over-the-counter antacids that contain aspirin such as, Alka-Seltzer Original, were developed to treat acid indigestion, body aches and headaches. Alka-Seltzer sold more than 300 million tablets in 2010. Aspirin-containing antacids usually contain 325-500 mg of aspirin plus 500 mg of sodium in some effervescent tablets. In 2009, FDA issued a warning about serious stomach bleeding risk with aspirin and other non-steroidal anti-inflammatory drugs (NSAIDs). Despite that warning, when FDA reviewed its Adverse Event Reporting System database, it found eight new cases of serious bleeding caused by aspirin-containing antacid products since that 2009 warning. In June 2016, FDA reissued the original warning. The patient is at higher risk for bleeding if they are 60 or older, have a history of stomach ulcers, take steroids or anticoagulants, or drink three or more alcoholic drinks every day.

References

1. *Gastroenterology, Pharmacist's Letter/Prescriber's Letter. August 2016; Volume 32*
2. FDA. Warning: Aspirin-Containing Antacid Medicines Can Cause Bleeding. June 6, 2016. http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm505110.htm . (Accessed September 06, 2016)
3. America's Greatest Brands. Alka Seltzer- Case Study. http://www.americasgreatestbrands.com/volume10/assets/AGB%20pdfs/AGB%20AlkaSeltzer.pdf (Accessed September 06, 2016).

Aptensio XR- New Extended Release Sprinkle Capsule

Aptensio XR® is an extended-release formulation of methylphenidate capsule with an onset of effect of 1 hour and 12-hour duration of effect with approximately 40% of the active ingredient released immediately and approximately 60% delivered later in the day. Aptensio XR is the first 12-hour sprinkle capsule. Aptensio XR can be sprinkled on applesauce and patients must be warned not to chew the sprinkles to avoid dose-dumping. Once-daily Aptensio XR is available in seven dose strengths (10, 15, 20, 30, 40, 50 and 60 mg).

References

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