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RPCC Pharmacy Forum

Special Interest Articles:

- Brintellix
- Cetylev
- Adzenys

Did you know?

In 2014, hydrocodone analgesic products were rescheduled to a more restrictive schedule II. Data results show that dispensed hydrocodone dropped by 16.0% in 2015.

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Brintellix- Antidepressant for Major Depressive Disorder

By Rachelle Reid, PharmD Candidate

Brintellix (vortioxetine) is a new antidepressant that was approved in 2013 and became available in United States pharmacies in 2014. It is FDA-approved to treat major depressive disorder (MDD). Although it is not fully understood how the drug's antidepressant effect works, it is thought to be related to its enhancement of serotonergic activity in the CNS through inhibition of the reuptake of serotonin (5-HT). Other activities of the drug include receptor antagonism and 5-HT_{1A} receptor agonism; however, it has not been established whether these activities contribute to the drug's antidepressant effect. Additionally, in vitro studies indicate that the drug is a 5-HT_{1D} and 5-HT_{7} receptor antagonist, and a 5-HT_{1B} receptor partial agonist, but clinical relevance of this is not known.

Brintellix (vortioxetine) is available in 5, 10, and 20 mg tablets. The recommended adult starting dose is 10 mg by mouth daily with or without food. If patients cannot tolerate this dose, he or she may decrease to 5 mg by mouth daily. The common adverse effects are nausea, vomiting, and diarrhea or constipation. Warnings and precautions include a black box warning for clinical worsening and suicide risk, serotonin syndrome, abnormal bleeding or bruising, hypomania, visual problems, and hyponatremia. Patients should not take this drug if they have hypersensitivity to vortioxetine, are currently taking a MAOI, have had a MAOI within 14 days of starting vortioxetine, or are taking linezolid or IV methylene blue. It is a pregnancy category C and should be discontinued in breastfeeding mothers. Patients taking CYP2D6 inhibitors or strong CYP inducers may require dose adjustment. Clinical trial experience regarding human overdosage is limited. Pre-marketing clinical study cases limited patients to those who accidentally or intentionally took up to a maximum dose of 40 mg. In men, the maximum single dose tested was 75 mg. Those who took the drug in the dose range of 40 to 75 mg saw increased rates of nausea, dizziness, diarrhea, abdominal discomfort, generalized pruritus, somnolence, and flushing.

Recommended treatment in an overdose may include: activated charcoal if patient is alert and overdose is recent, monitor vital signs (including temperature) and mental status, and symptomatic and supportive care.

Cetylev (acetylcysteine) – New Drug Approval

On February 9, 2016, Arbor Pharmaceuticals announced the FDA approval of Cetylev (acetylcysteine) effervescent tablets for oral solution, to prevent or lessen hepatic injury after ingestion of a potentially hepatotoxic quantity of acetaminophen in patients with acute ingestion or from repeated supratherapeutic ingestion. According to the American Association of Poison Control Centers, acetaminophen overdoses accounted for 108 deaths in 2014 from a reported 73,347 exposures. The most common adverse events with Cetylev use were nausea and vomiting, other gastrointestinal symptoms, and rash with or without fever. The recommended dosage of Cetylev for adult and pediatric patients is an oral loading dose of 140 mg/kg. The maintenance dosage is 70 mg/kg and repeated every 4 hours for a total of 17 doses. Cetylev effervescent tablets are prepared by dissolving the appropriate number of tablets in a specified volume of water as instructed by the drug label. The solution will have a lemon-mint tasting flavor. It is for oral administration only and not to be administered via nebulization or intratracheal instillation. Arbor Pharmaceuticals' launch plans for Cetylev are pending. Cetylev will be available as 500 mg and 2.5 gram effervescent tablets. One thing to note, Cetylev has a very similar sounding name and spelling to the drug Cetlev (levocetirizine - antihistamine). Medical professionals will need to be aware of the very similar names when prescribing.

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FDA Okays First Orally Disintegrating Tablet for ADHD in Kids

The US Food and Drug Administration (FDA) has approved an amphetamine extended-release orally disintegrating tablet (Adzenys XR-ODT) for the treatment of attention-deficit/hyperactivity disorder (ADHD) in children aged 6 years and older.

Adenys XR- ODT was approved by the FDA on the basis of data demonstrating that the drug is bioequivalent of the previously approved mixed amphetamine salts extended-release capsules (Adderall XR), one of the most commonly prescribed medications for the treatment of ADHD. Adzenys XR-ODT will be available in six dosage strengths, equivalent to the Adderall XR dosage strengths, thus allowing providers to individualize the dose. Product shipments will begin in the second quarter of 2016.

Equivalent Doses:

Adezenys XR-ODT	Adderall XR
3.1 mg	5 mg
6.3 mg	10 mg
9.4 mg	15 mg
12.5 mg	20 mg
15.7 mg	25 mg
18.8 mg	30 mg