

ToxUpdate

Regional Poison Control Center, Birmingham, AL

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Lucemyra™: The First FDA Approved Non-Opioid Drug for Alleviation of Opioid Withdrawal Symptoms in Adults

By Jonathan Tucker, Samford University PharmD Candidate

The opioid epidemic has affected people of all races and ages in the United States. In 2017, there were more than 47,000 people that died from opioid overdoses. One of the main reasons people hesitate to seek help with opioid addiction is fear of withdrawal. People experiencing opioid withdrawals may have symptoms such as agitation, anxiety, sleep issues, drug cravings, muscle aches, runny nose, sweating, nausea, vomiting, and diarrhea.

In May of 2018, Lucemyra (lofexidine hydrochloride) was approved by the FDA for the mitigation of opioid withdrawal symptoms to facilitate abrupt discontinuation of opioids in adults. Lucemyra is a central alpha 2-agonist that works by binding to receptors on adrenergic neurons causing a decrease in sympathetic tone and a reduction in the release of norepinephrine. This is beneficial because it is believed that norepinephrine is associated with many of the symptoms of opioid withdrawal.

Patients taking Lucemyra should start treatment by taking a dose of three 0.18 mg tablets by mouth four times daily with 5-6 hours between doses during the peak of withdrawal symptoms. This is usually the first 5 to 7 days since last opioid use. Lucemyra can be taken for up to 14 days and, according to product labeling, there should be a reduction in dose by 1 tablet every 1 to 2 days. The clinical efficacy of Lucemyra was supported by 2 randomized, double-blind, placebo-controlled clinical trials looking at patients who were physically dependent on opioids and were undergoing discontinuation of the opioid medication. The main endpoint in both studies to back clinical efficacy, was the Short Opiate Withdrawal Scale of Gossop (SOWS-Gossop) total score. The two studies both exhibited a statistically significant difference between Lucemyra and the placebo.

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Special Interest Articles

- Lucemyra
- Dsuvia
- Primatene Mist

Did you know?

In summer of 2018, the FDA reported that some generic angiotensin II receptor blocker (ARB) medicines contain N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA), most likely human carcinogens. It has been determined that the impurities may be produced when specific chemicals and reaction conditions are present in the manufacturing process, such as reuse of solvents. NDMA's properties make it hard to detect in standard laboratory testing. Tests have now been developed to detect NDMA and NDEA in all ARB medicines.

Dsuvia™: First FDA Approved Orally Administered Sufentanil Product

By Mandi Woodruff, Samford University PharmD Candidate

“This medication is only to be administered in a medically supervised healthcare setting, such as hospitals, surgical centers, and emergency departments.”



Dsuvia (sufentanil) is the first FDA approved (11/2018) orally administered sufentanil product for the treatment of acute pain that is severe enough to require an opioid analgesic in which alternative treatments are not adequate. This medication is only to be administered in a medically supervised healthcare setting, such as hospitals, surgical centers, and emergency departments. Dsuvia binds to opioid receptors throughout the CNS, resulting in the opening of potassium channels and inhibition of calcium channels. This increases the pain threshold and alters the perception of pain.

Dsuvia is available as a 30 mcg sublingual tablet in a single-dose, pre-filled applicator. It is to be given as needed with a minimum of 1 hour between doses and a maximum of 12 tablets in 24 hours. In a recent study, 161 patients were randomized in a double-blind, placebo-controlled trial and received either Dsuvia 30 mcg or placebo as needed with a minimum of 60 minutes in between doses. Patients receiving Dsuvia had a statistically significant greater pain intensity reduction from baseline compared to placebo. Only 22% of those receiving Dsuvia required rescue-medication within the first 12 hours of treatment, compared to 65% seen with placebo.

The most commonly reported adverse effects seen with Dsuvia are nausea, vomiting, dizziness, headache, and hypotension. Contraindications to therapy include: significant respiratory depression, acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment, known or suspected gastrointestinal obstruction (including paralytic ileus), and known hypersensitivity to sufentanil or components of Dsuvia. Avoid use with mixed agonist/antagonist and partial agonist opioid analgesics because they may reduce the analgesic effect of Dsuvia or precipitate withdrawal symptoms.

One overdose had been reported with sufentanil via intrathecal administration. Pruritus and difficulty swallowing were reported, with no respiratory depression or alterations in vital signs. So far, no overdoses have been reported with the oral formulation. Treatment of an overdose should consist of activated charcoal (with early ingestion and asymptomatic), supportive measures including oxygen and ventilation for respiratory depression, and naloxone (opioid antagonist) for severe toxicity.

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Primatene Mist Inhalation Back on the Shelves

By Laura Read RPh, CSPI, Regional Poison Control Center

After seven years, Primatene Mist has returned as an over-the-counter (OTC) inhaler for people with mild asthma. The product was removed from the market in 2011 because it contained chlorofluorocarbon (CFC) propellants, which are known to harm the ozone. Environmental regulations were set forth in 1987 by the **Montreal Protocol** to globally protect the stratospheric ozone layer by phasing out production of certain substances. Before Primatene Mist was removed from the market, it had been available for 50 years.

Primatene Mist is the only approved OTC asthma inhaler in the United States. The active ingredient is 0.125 mg of epinephrine per spray and uses hydrofluoroalkane (HFA) propellants instead of the CFC propellants. It features a built-in spray indicator and metal canister, replacing the glass container in original Primatene Mist. The FDA approved Primatene Mist for those who have been diagnosed with asthma by a health care provider and are \geq 12 years of age.

Supporters say that OTC Primatene Mist gives asthma patients easier access to quick-relief medications. However, some national groups like the National Asthma Education and Prevention Program (NAEPP), recommend against the use of epinephrine for treatment of asthma exacerbations, pointing out that it has potential for excessive cardiac stimulation.

An article in *Chest*, the journal of the American College of Chest Physicians, concluded that occasional use of OTC epinephrine inhalers appears to be safe as long as used as directed per label. However, the authors went on to say that 20% of those using the OTC epinephrine inhalers, should not be using them and should be under the care of a healthcare provider.

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Lucemrya Continued from Page 1:

The most common adverse effects of Lucemrya are bradycardia, dizziness, dry mouth, hypotension, orthostatic hypotension, sedation, and somnolence. Some other effects that may occur are QT prolongation, syncope, and tinnitus. Safety and efficacy has not yet been proven in people less than 17 years of age. There have been no reported cases of any overdoses; however, it is anticipated that effects of overdose would be similar to adverse effects.

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Mandi Woodruff and Jonathan Tucker, Samford Pharmacy Students, visited Kimberly Senior Center and did a presentation on Medication Safety, January 31, 2019.