

Pfizer and Acura Announce FDA Approval of OXECTA™

Pfizer and Acura Pharmaceuticals has received FDA approval for Oxecta™, a new immediate-release formulation of oxycodone that may help prevent the potential for abuse. This new pain medication has been approved and may reduce the abuse potential seen with many of the opioid agonists. Oxecta™ is a schedule II narcotic analgesic used for the management of acute and chronic moderate to severe pain where the use of an opioid analgesic is appropriate.

Oxecta™ is formulated with Aversion® technology, licensed by Acura Pharmaceuticals, which creates a unique combination of pharmaceutical ingredients that helps reduce the abuse potential from crushing, snorting or injecting the medication. Aversion® technology causes the active ingredients to gel, forming clumps instead of powder when crushed to prevent injection, and to irritate the nasal passages to prevent inhalation. While it should help reduce the potential for abuse, Pfizer has noted that the potential for abuse is still present, both by these methods and orally. They have also stated that there is no evidence of Oxecta™ having a reduced abuse potential compared to immediate-release oxycodone.

The dosage for patients who have not been receiving opioid analgesics is 5 to 15 mg every 4 to 6 hours as needed, and it is supplied as 5 mg and 7.5 mg tablets. It may be taken with or without food. Oxecta™ is contraindicated in patients with respiratory depression in unmonitored settings, paralytic ileus, acute or severe asthma and hypersensitivity to oxycodone. Patients should avoid consuming alcohol or taking any sedative or CNS depressant while taking Oxecta™. Common side effects are drowsiness, nausea/vomiting, constipation, headache and itching. If patients are stopping therapy after taking for chronic pain for more than a few weeks, they should taper the dose over time to avoid withdrawal symptoms.

Oxecta™ is the newest development in abuse-reducing narcotic medications. While it does not completely eliminate the potential for abuse, it is a new step for this class of opioid agonists and an interesting alternative for acute and chronic pain management. This medication is expected to be available in pharmacies during Q3 or Q4 2011.

