Troxyca® ER (oxycodone/naltrexone) – New Drug Approval

- On August 19, 2016, Pfizer announced the FDA approval of Troxyca ER (oxycodone/naltrexone) for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.
    - Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, Troxyca ER should be reserved for use in patients for whom alternative treatment options (eg, non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
    - Troxyca ER is not indicated as an as-needed (prn) analgesic.
    - Troxyca ER is a Schedule II controlled substance.
- Troxyca ER has properties that are expected to reduce abuse when crushed and administered by the oral and intranasal routes.
    - Troxyca ER contains pellets that consist of oxycodone, an opioid agonist, which surround sequestered naltrexone, an opioid antagonist.
    - When taken as directed, the naltrexone remains sequestered while the patient receives extended-release oxycodone.
    - When the pellets are crushed, naltrexone is released which counteracts the effects of oxycodone.
    - The abuse-deterrent features of Troxyca ER were demonstrated in *in vitro* laboratory studies and three clinical abuse-potential studies.
- The efficacy of Troxyca ER was based on a randomized, placebo-controlled trial in 281 patients with moderate-to-severe chronic low back pain.
    - The mean change in the weekly average pain intensity numerical rating scale (NRS) scores from baseline to the average of weeks 11 and 12 was statistically significantly superior for those treated with Troxyca ER compared to placebo.
- Troxyca ER is contraindicated in patients with significant respiratory depression, acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment, and known or suspected gastrointestinal obstruction, including paralytic ileus.
- Troxyca ER carries a boxed warning regarding the following: addiction, abuse, and misuse; life-threatening respiratory depression; accidental ingestion; neonatal opioid withdrawal syndrome; and cytochrome P450 3A4 interaction.
- Other warnings and precautions of Troxyca include risks due to interactions with central nervous system depressants; life-threatening respiratory depression in patients with chronic pulmonary disease or in elderly, cachectic, or debilitated patients; adrenal insufficiency; severe hypotension; risks of use in patients with increased intracranial pressure, brain tumors, head injury, or impaired consciousness; risks of use in patients with gastrointestinal conditions; increased risk of seizures in patients with seizure disorders; withdrawal; risks of driving and operating machinery; and laboratory tests and monitoring.

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- The most common adverse events with Troxyca ER use were nausea, constipation, vomiting, headache, and somnolence.
- The recommended dose of Troxyca ER in opioid naïve and opioid non-tolerant patients is 10 mg/1.2 mg every 12 hours.
    - Dosing is based on the patient's severity of pain, response to therapy, prior analgesic experience, and risk factors for addiction, abuse, and misuse.
    - The lowest effective dose should be used for the shortest duration consistent with individual patient treatment goals.
    - Patients should not crush, chew, or dissolve the pellets in the capsule to avoid the risk of release and absorption of a potentially fatal dose of oxycodone and to avoid release of sequestered naltrexone that could precipitate opioid withdrawal.
- Pfizer plans to launch Troxyca ER in the first quarter of 2017. Troxyca ER (oxycodone/naltrexone) will be available as 10 mg/1.2 mg, 20 mg/2.4 mg, 30 mg/3.6 mg, 40 mg/4.8 mg, 60 mg/7.2 mg and 80 mg/9.6 mg extended-release capsules.