RoxyBond™ (oxycodone) – New drug approval

- On April 26, 2017, Inspirion Delivery Sciences announced the FDA approval of RoxyBond (oxycodone) for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

    — RoxyBond is a Schedule 2 (C-II) controlled substance.
    — Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, RoxyBond should be reserved for use in patients for whom alternative treatment options (eg, non-opioid analgesics or opioid combination products) have not been or are not expected to be tolerated, or have not provided or are not expected to provide adequate analgesia.

- RoxyBond is an abuse-deterrent formulation of immediate-release (IR) oxycodone that uses physical and chemical barriers to make the tablet more difficult to manipulate for misuse and abuse even if the tablet is subjected to physical manipulation and/or attempts at chemical extraction.

    — Laboratory tests demonstrated that, relative to other oxycodone IR tablets, RoxyBond has increased resistance to cutting, crushing, grinding, or breaking. Both intact and manipulated RoxyBond tablets resisted extraction in selected household and laboratory solvents under various conditions.
    — Relative to other oxycodone IR tablets, the RoxyBond formulation forms a viscous material that resists passage through a needle; it was also more difficult to prepare solutions suitable for intravenous (IV) injection.
    — In vitro data demonstrated that RoxyBond has physicochemical properties expected to make abuse via injection difficult. However, abuse by the intranasal, oral, and IV route is still possible.
    — An in vivo intranasal clinical abuse potential study was also conducted.

- RoxyBond carries a boxed warning for addiction, abuse, and misuse; life threatening respiratory depression; accidental ingestion; neonatal opioid withdrawal syndrome; cytochrome P450 3A4 interaction; and risks from concomitant use with benzodiazepines or other central nervous system depressants.

- RoxyBond is contraindicated in patients with significant respiratory depression; acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment or hypercarbia; known or suspected gastrointestinal obstruction, including paralytic ileus; and known hypersensitivity to oxycodone.

- Other warnings and precautions of RoxyBond include 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; and risks of driving and operating machinery.

- The most common adverse reactions (≥ 3%) with RoxyBond use were nausea, constipation, vomiting, headache, pruritus, insomnia, dizziness, asthenia, and somnolence.

- The dosing regimen for each patient should be individualized, taking into account the patient's severity of pain, patient response, prior analgesic treatment experience, and risk factors for

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addiction, abuse, and misuse. The recommended starting dose of RoxyBond is 5 to 15 mg orally every 4 to 6 hours as needed for pain.

  - The lowest effective dose should be used for the shortest duration that is consistent with individual patient treatment goals.
  - Consult the product information for dosing recommendations for patients converting from other opioids to RoxyBond.

- Inspirion Delivery Sciences' launch plans for RoxyBond are pending. RoxyBond will be available as 5 mg, 15 mg and 30 mg tablets.