Nucynta® (tapentadol) – Expanded indication

- On July 3, 2023, the FDA approved Collegium Pharmaceutical's Nucynta (tapentadol), for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate in adults and pediatric patients aged 6 years and older with a body weight of at least 40 kg.
    - Nucynta was previously approved for this indication in adults only.
- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dose or duration, Nucynta should be reserved for use in patients for whom alternative treatment options (eg, nonopioid analgesics or opioid combination products):
    - Have not been tolerated, or are not expected to be tolerated
    - Have not provided adequate analgesia, or are not expected to provide adequate analgesia
- The approval of Nucynta for the expanded indication was based on a randomized, double-blind, placebo-controlled, multiple-dose efficacy and safety study of Nucynta oral solution in 175 pediatric patients from birth to 17 years of age who had undergone surgery that would reliably produce moderate to severe pain and supported by pharmacokinetic and safety data from three open-label, single-dose studies of Nucynta oral solution in 129 patients from birth to 17 years of age with moderate to severe acute pain from a surgical procedure.
- Nucynta carries a boxed warning for addiction, abuse, and misuse; life-threatening respiratory depression; accidental ingestion; risks from concomitant use with benzodiazepines or other central nervous system depressants; neonatal opioid withdrawal syndrome; and opioid analgesic Risk Evaluation and Mitigation Strategy (REMS).
- The most common adverse reactions (≥ 5%) with Nucynta use in pediatric patients were vomiting, constipation, nausea, pruritus, and pyrexia.
- Refer to the Nucynta drug label for complete dosing and administration recommendations for both pediatric patients and adults.

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