Seglentis® (celecoxib/tramadol) – New drug approval

- On October 18, 2021, Esteve Pharmaceuticals announced the FDA approval of Seglentis (celecoxib/tramadol), for the management of acute pain in adults that is severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

    - Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, Seglentis should be reserved for use in patients for whom alternative treatment options (eg, non-opioid analgesics): (1) have not been tolerated or are not expected to be tolerated; or (2) have not provided adequate analgesia or are not expected to provide adequate analgesia.

- Both active ingredients for Seglentis, celecoxib and tramadol, are currently available generically as single-ingredient products.

- The efficacy of Seglentis was established in one randomized, double-blind study in 637 patients 18 years of age or older with acute postoperative pain following unilateral first metatarsal osteotomy with internal fixation. Patients were randomized to Seglentis, tramadol, celecoxib, or placebo. The primary endpoint was time-weighted summed pain intensity difference over 48 hours (SPID48).

    - Patients in the Seglentis group had statistically significantly better mean SPID48 scores than any of the other groups after bunionectomy.

- Seglentis carries boxed warnings for addiction, abuse and misuse; risk evaluation and mitigation strategy; life-threatening respiratory depression; accidental ingestion; cardiovascular thrombotic events; gastrointestinal bleeding, ulceration, and perforation; ultra-rapid metabolism of tramadol and other risk factors for life-threatening respiratory depression in children; neonatal opioid withdrawal syndrome; interactions with drugs affecting cytochrome P450 isoenzymes; risks from concomitant use with benzodiazepines or other central nervous system depressants.

- Seglentis is contraindicated in:

    - All patients younger than 12 years of age
    - Post-operative management in children younger than 18 years of age following tonsillectomy and/or adenoidectomy.

- Seglentis is also contraindicated in patients with:

    - Significant respiratory depression
    - In the setting of coronary artery bypass graft surgery
    - Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment
    - Known or suspected gastrointestinal obstruction, including paralytic ileus
    - Previous hypersensitivity to tramadol, opioids, celecoxib, sulfonamides, or any other component of the drug product
    - Concurrent use of monoamine oxidase inhibitors or use within the last 14 days
    - History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs). Severe, sometimes fatal, anaphylactic reactions to NSAIDs, have been reported in such patients.

- For additional warnings and precautions, refer to the drug label for Seglentis.

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- The most common adverse reactions (> 5% and > placebo) with Seglentis use were nausea, vomiting, dizziness, headache, and somnolence.

- The recommended dose of Seglentis is two tablets (each containing 56 mg celecoxib and 44 mg tramadol) every 12 hours as needed for pain.

    — Seglentis should be used for the shortest duration consistent with individual patient treatment goals.
    — Seglentis should not be used with other celecoxib- or tramadol-containing products.
    — The recommended dose of Seglentis should not be exceeded.

- Seglentis will be commercialized in the U.S. by KOWA Pharmaceuticals America and launch plans are pending. Seglentis will be available as a fixed-dose tablet containing 56 mg celecoxib and 44 mg tramadol hydrochloride.