Dsuvia™ (sufentanil) – New drug approval

- On November 2, 2018, AcelRx announced the FDA approval of Dsuvia (sufentanil) for use in adults in a certified medically supervised healthcare setting, such as hospitals, surgical centers, and emergency departments, for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

    - Not for home use or for use in children. Treatment with Dsuvia should be discontinued before patients leave the certified medically supervised healthcare setting.
    - Not for use for more than 72 hours. The use of Dsuvia beyond 72 hours has not been studied.
    - Only to be administered by a healthcare provider.
    - Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, Dsuvia should be reserved for use in patients for whom alternative treatment options (eg, non-opioid 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.

- Dsuvia is a Schedule II controlled substance.

- Dsuvia is a sublingual formulation of sufentanil that's delivered through a disposable, pre-filled, single-dose applicator.

    - Dsuvia has some unique features in that the drug is delivered in a stable form that makes it ideally suited for certain special circumstances where patients may not be able to swallow oral medication, and where access to intravenous (IV) pain relief is not possible (eg, use on the battlefield, obese, elderly, burn or needle-phobic patients).

- The efficacy and safety of Dsuvia were evaluated in one randomized, double-blind, placebo-controlled trial which enrolled 161 patients with acute postoperative pain after abdominal surgery (studied up to 48 hours). Patients were dosed with Dsuvia or placebo as needed with a minimum of 60 minutes between doses. Morphine sulfate 1 mg IV was available as rescue medication. The primary efficacy endpoint was the time-weighted summed pain intensity difference over 12 hours (SPID12).

    - Patients using Dsuvia had a statistically significantly higher SPID12 than patients using placebo.
    - The median time to onset of meaningful pain relief was 54 minutes for Dsuvia vs. 84 minutes for placebo.
    - Approximately 22% of patients in the Dsuvia group and 65% of patients in the placebo group took rescue medication within the first 12 hours of the treatment phase.

- Dsuvia carries a boxed warning for accidental exposure; life-threatening respiratory depression; addiction, abuse, and misuse; cytochrome P450 3A4 interaction; and risks from concomitant use with benzodiazepines or other central nervous system depressants. Dsuvia will only be available through the Dsuvia Risk Evaluation and Mitigation Strategy Program (REMS).

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

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- Other warnings and precautions of Dsuvia include life threatening respiratory depression in patients with chronic pulmonary disease or in elderly, cachectic, or debilitated patients; serotonin syndrome with concomitant use of serotonergic drugs; 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; bradycardia; and neonatal opioid withdrawal syndrome.

- The most commonly reported adverse reactions (≥ 2%) with Dsuvia use were nausea, headache, vomiting, dizziness, and hypotension.

- The recommended dosage of Dsuvia is 30 mcg sublingually as needed with a minimum of 1 hour between doses. Do not exceed 12 tablets in 24 hours.

    — The maximum cumulative daily dose of sufentanil is 360 mcg or 12 tablets (12 tablets x 30 mcg/dose).

- Dsuvia will not be available in retail pharmacies or for outpatient use. Dsuvia will only be distributed to healthcare settings certified in the Dsuvia REMS program following attestation by an authorized representative that the healthcare setting will comply with appropriate dispensing and use restrictions of Dsuvia.

    — As part of the REMS program, AcelRx will monitor distribution and audit wholesalers' data, evaluate proper usage within the healthcare settings and monitor for any diversion and abuse. Additionally, AcelRx will de-certify healthcare settings that are non-compliant with the REMS program.

- AcelRx plans to launch Dsuvia in the first quarter of 2019. Dsuvia will be available as a 30 mcg sublingual tablet housed in a disposable, single-dose applicator.

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