Dsuvia (sufentanil)

NEW PRODUCT SLIDESHOW

MPR
Introduction

- **Brand name:** Dsuvia
- **Generic name:** Sufentanil
- **Pharmacological class:** Opioid agonist
- **Strength and Formulation:** 30mcg; sublingual tabs (housed in a disposable, single-dose applicator); contains mannitol
- **Manufacturer:** AcelRx Pharmaceuticals
- **How supplied:** SL tabs—10 pouches per carton
- **Legal Classification:** CII
Dsuvia
For use in adults in a **certified medically supervised healthcare setting** (e.g., hospitals, surgical centers, emergency departments) for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.
Limitations of Use

- **Not** for home use or for children; discontinue treatment before leaving supervised healthcare setting
- **Not** for use >72hrs
- **Only** for administration by healthcare provider
- **Reserve for use** in patients for whom alternative options have not been or are not expected to be tolerated, or have not or are not expected to provide adequate analgesia
Dsuvia REMS

- Healthcare settings that dispense Dsuvia must:
  - Be able to manage an acute opioid overdose including respiratory depression
  - Train all relevant staff that Dsuvia must not be dispensed for use outside of the certified healthcare setting
  - Train all relevant staff involved in administration of Dsuvia to refer to the Directions for Use prior to administration
  - Establish processes and procedures to verify that Dsuvia is not dispensed for use outside of the certified healthcare setting
Dosage & Administration

- Do not chew or swallow tab
- Avoid eating, drinking, talking for 10mins after dose
- Administer via single-dose applicator by healthcare provider
- **30mcg** SL as needed with ≥1hr between doses; max 12 tabs in 24hrs
- Max cumulative daily dose: 360mcg (12 tabs)
Considerations for Special Populations

- **Pregnancy**: Potential neonatal opioid withdrawal syndrome with prolonged use
- **Labor & delivery**: Not recommended
- **Nursing mothers**: Consider benefits/risks; monitor infants
- **Pediatric**: Not established
- **Elderly**: Monitor for CNS and respiratory depression
- **Hepatic or renal impairment**: Monitor closely
Contraindications

- Significant respiratory depression
- Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment
- Known or suspected GI obstruction, including paralytic ileus
Boxed Warning

- Accidental exposure
- Dsuvia REMS program
- Life-threatening respiratory depression
- Addiction, abuse, and misuse
- Cytochrome P450 3A4 interaction
- Risks from concomitant use with benzodiazepines or other CNS depressants
Warnings/Precautions

- Life-threatening respiratory depression; monitor closely (esp. during initiation)
- Accidental exposure may cause fatal overdose (esp. in children)
- COPD, cor pulmonale, decreased respiratory reserve, hypoxia, hypercapnia, pre-existing respiratory depression; monitor and consider non-opioid analgesics
Warnings/Precautions

- Abuse potential (monitor)
- Adrenal insufficiency
- Head injury
- Increased intracranial pressure, brain tumors; monitor
- Seizure disorders
- CNS depression
- Impaired consciousness, coma, shock; avoid
Warnings/Precautions

- Biliary tract disease
- Acute pancreatitis
- Bradyarrhythmias
- Drug abusers
- Reevaluate periodically
- Avoid abrupt cessation
- Elderly, cachectic, debilitated
Interactions

- Increased risk of hypotension, respiratory depression, sedation with benzodiazepines or other CNS depressants (e.g., non-benzodiazepine sedatives/hypnotics, anxiolytics, general anesthetics, phenothiazines, tranquilizers, muscle relaxants, antipsychotics, alcohol, other opioids)
  - Reserve concomitant use in those for whom alternative options are inadequate; limit dosages/durations to minimum required; monitor
Interactions

- During or within 14 days of **MAOIs**: not recommended
- Risk of **serotonin syndrome** with serotonergic drugs (eg, SSRIs, SNRIs, TCAs, triptans, 5-HT₃ antagonists, mirtazapine, trazodone, tramadol, MAOIs, linezolid, IV methylene blue); monitor and discontinue if suspected
Interactions

- **Avoid** concomitant mixed agonist/antagonist opioids (eg, butorphanol, nalbuphine, pentazocine) or partial agonist (eg, buprenorphine); may reduce effects and precipitate withdrawal symptoms
- **Potentiated** by CYP3A4 inhibitors (eg, macrolides, azole antifungals, protease inhibitors); monitor
Interactions

- Antagonized by CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin); monitor
- May antagonize diuretics; monitor
- **Paralytic ileus** may occur with anticholinergics
Adverse Reactions

- Nausea
- Headache
- Vomiting
- Dizziness
- Hypotension
- Respiratory depression
- Syncope
Mechanism of Action

- Sufentanil is relatively selective for the mu-opioid receptor, although it can bind to other opioid receptors at higher doses.
- Its therapeutic action is thought to be mediated through opioid-specific receptors throughout the CNS.
- There is no ceiling effect to analgesia.
Clinical Studies

- The efficacy and safety of Dsuvia were evaluated in a randomized, double-blind, placebo-controlled trial (N=161) of adults with acute post-op pain after abdominal surgery (Study SAP301)
- Patients received Dsuvia 30mcg or placebo as needed with at least 1hr between doses
The primary efficacy endpoint was the time-weighted summed pain intensity difference over 12 hours (SPID12)
Clinical Studies

- Patients who received Dsuvia had a statistically significantly higher SPID12 vs patients who received placebo.
- Median time to onset of meaningful pain relief was **54 minutes** for the Dsuvia group vs **84 minutes** for the placebo group.
- For more clinical trial data, see full labeling.
New Product Monograph

- For more information view the product monograph available at:
  
  https://www.empr.com/drug/dsuvia/