Generic Name:
Sufentanil
Trade Name:
Dsuvia
Company:
AcelRx
Notes:

On November 2, AcelRx announced FDA approval of sufentanil for management of acute pain severe enough to require an opioid analgesic for adult patients in certified medically supervised health care settings, such as hospitals, surgical centers, and emergency departments.

It is the first and only sufentanil sublingual tablet approved for acute pain in health care settings and will not be available in retail pharmacies or for outpatient use, according to AcelRx in a news release. Health care settings must be certified in a sufentanil Risk Evaluation and Mitigation Strategy (REMS) program following attestation by an authorized representative that the health care setting will comply with appropriate dispensing and use restrictions.

As part of the REMS program, AcelRx will monitor distribution and audit wholesalers' data, evaluate proper use within the health care settings, and monitor for any diversion and abuse. In addition, AcelRx will decertify health care settings that are noncompliant with the REMS program.

The 30-mcg sufentanil tablet comes in a single-dose, prefilled applicator for sublingual administration.

Approval was based on a randomized, double-blind, placebo-controlled clinical study demonstrating a statistically greater summed pain intensity difference from baseline over the first 12 hours of the study compared with placebo. The pain intensity difference from baseline was superior to that of the placebo group within 15 minutes, and median meaningful pain relief occurred following a single dose.

The single-strength tablet and single-unit packaging are designed to mitigate the possibility of dosing errors, misuse, and diversion. The sublingual administration makes the opioid an option for patients with nothing-by-mouth status and patients with difficult I.V. access (e.g., obese, older adults, burn, needle-phobic).

Medication Monitor Categories:
New Drug Approvals