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**Generic Name:**

Buprenorphine and naloxone

**Trade Name:**

Suboxone

**Company:**

Mylan Technologies, Dr. Reddy's Laboratories

**Notes:**

FDA approved the [first generic versions](#) of Suboxone (buprenorphine and naloxone) sublingual film for the treatment of opioid dependence.

[Medication-assisted treatment \(MAT\)](#) is a comprehensive approach that combines FDA-approved medications (currently methadone, buprenorphine, or naltrexone) with counseling and other behavioral therapies to treat patients with opioid use disorder (OUD). Regular adherence to MAT with buprenorphine reduces opioid withdrawal symptoms and the desire to use opioids, without causing the cycle of highs and lows associated with opioid misuse or abuse.

At proper doses, buprenorphine also decreases the pleasurable effects of other opioids, making continued opioid abuse less attractive. According to the Substance Abuse and Mental Health Services Administration, patients receiving MAT for treatment of their OUD cut their risk of death from all causes in half.

One of the ways FDA is encouraging access and wider use of MAT is through the approval of generic versions of these products. Generic drugs approved by FDA have, among other things, the same quality as brand-name drugs. Generic drug manufacturing and packaging sites must meet the same quality standards as those of brand-name drugs.

Adverse events commonly observed with the buprenorphine and naloxone sublingual film are oral hypoesthesia (numbness), glossodynia (burning mouth), oral mucosal erythema (inflammation of oral mucous membrane), headache, nausea, vomiting, hyperhidrosis (excessive sweating), constipation, signs and symptoms of withdrawal, insomnia, pain, and peripheral edema (accumulation of fluid causing swelling in lower limbs). These products may only be prescribed by Drug Addiction Treatment Act (DATA)-certified prescribers.

Mylan Technologies and Dr. Reddy's Laboratories received approval to market buprenorphine and naloxone sublingual film in multiple strengths. Buprenorphine and naloxone sublingual film should be used as part of a complete treatment plan that includes counseling and psychosocial support.

**Medication Monitor Categories:**

[Supplemental Approvals](#)

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