FIRST TIME GENERIC APPROVAL

Brand Name	Buprenorphine Hydrochloride
Generic Name	buprenorphine hydrochloride
Drug Manufacturer	Alvogen, Inc.

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

August 3, 2021

LAUNCH DATE

N/A

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 211594

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Buprenorphine buccal film contains buprenorphine, a partial opioid agonist. buprenorphine buccal film is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

MECHANISMS OF ACTION

Buprenorphine is a partial agonist at the mu-opioid receptor and an antagonist at the kappa-opioid receptor.

DOSE FORM AND STRENGTH

Buccal film available in 75 mcg, 150 mcg, 300 mcg, 450 mcg, 600 mcg, 750 mcg, and 900 mcg dosage strengths.

DOSE & ADMINISTRATION

- To be prescribed only by health care providers knowledgeable in use of potent opioids for management of chronic pain.
- Use the lowest effective dosage for the shortest duration consistent with individual patient treatment goals.
- Individualize dosing based on the severity of pain, patient response, prior analgesic experience, and risk factors for addiction, abuse, and misuse.

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- Discuss availability of naloxone with the patient and caregiver and assess each patient's need for access to naloxone, both when initiating and renewing treatment with buprenorphine buccal film. Consider prescribing naloxone based on the patient's risk factors for overdose.
- **For opioid-naïve patients:** Initiate therapy with 75 mcg buprenorphine buccal film once daily or every 12 hours, as tolerated, for at least 4 days before increasing dose to 150 mcg every 12 hours.
- **Conversion from other opioids to buprenorphine buccal film:** Taper current daily opioid dose to 30 mg oral morphine sulfate equivalents (MSE) or less prior to initiating therapy with buprenorphine buccal film.
  - For patients taking less than 30 mg oral MSE, initiate therapy with 75 mcg once daily or every 12 hours.
  - For patients taking between 30 mg and 89 mg oral MSE, initiate therapy with 150 mcg buprenorphine buccal film every 12 hours following analgesic taper.
  - For patients taking between 90 mg and 160 mg oral MSE, initiate therapy with 300 mcg buprenorphine buccal film every 12 hours following analgesic taper.
  - For patients taking greater than 160 mg oral MSE, consider alternate analgesic.
- Buprenorphine buccal film doses of 600 mcg, 750 mcg, and 900 mcg are only for use following titration from lower doses of buprenorphine buccal film.
- Do not abruptly discontinue buprenorphine buccal film in a physically dependent patient because rapid discontinuation of opioid analgesics has resulted in serious withdrawal symptoms, uncontrolled pain, and suicide.
- **Patients with Severe Hepatic Impairment:** Reduce the starting and incremental dose by half that of patients with normal liver function.
- **Patients with Oral Mucositis:** Reduce the starting and incremental dose by half that of patients without mucositis.