Belbuca

(buprenorphine)

New Product Slideshow

MPR

Introduction

- **Brand name:** Belbuca
- **Generic name:** Buprenorphine
- **Pharmacological class:** Partial opioid agonist
- **Strength and Formulation:** 75mcg, 150mcg, 300mcg, 450mcg, 600mcg, 750mcg, 900mcg; buccal films; peppermint flavor
- **Manufacturer:** Endo
- **How supplied:** Films—60
- **Legal Classification:** CIII

BELBUCA


NDC 63481-207-01
Contains 1 Buccal Film
Belbuca™
(buprenorphine hydrochloride)
buccal film
150 mcg
Each buccal film contains: 150 mcg of buprenorphine
Usual Dosage: See package insert for complete prescribing information.
Use entire film. Do not cut, tear, chew or swallow film.
Keep Belbuca out of sight and reach of children.
Children who accidentally take Belbuca will need emergency medical care.
℞ only


NDC 63481-348-01
Contains 1 Buccal Film
Belbuca™
(buprenorphine hydrochloride)
buccal film
300 mcg
Each buccal film contains: 300 mcg of buprenorphine
Usual Dosage: See package insert for complete prescribing information.
Use entire film. Do not cut, tear, chew or swallow film.
Keep Belbuca out of sight and reach of children.
Children who accidentally take Belbuca will need emergency medical care.
℞ only


NDC 63481-519-01
Contains 1 Buccal Film
Belbuca™
(buprenorphine hydrochloride)
buccal film
450 mcg
Each buccal film contains: 450 mcg of buprenorphine
Usual Dosage: See package insert for complete prescribing information.
Use entire film. Do not cut, tear, chew or swallow film.
Keep Belbuca out of sight and reach of children.
Children who accidentally take Belbuca will need emergency medical care.
℞ only


NDC 63481-161-01
Contains 1 Buccal Film
Belbuca™
(buprenorphine hydrochloride)
buccal film
75 mcg
Each buccal film contains: 75 mcg of buprenorphine
Usual Dosage: See package insert for complete prescribing information.
Use entire film. Do not cut, tear, chew or swallow film.
Keep Belbuca out of sight and reach of children.
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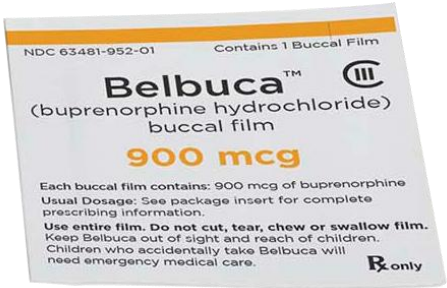
℞ only


NDC 63481-685-01
Contains 1 Buccal Film
Belbuca™
(buprenorphine hydrochloride)
buccal film
600 mcg
Each buccal film contains: 600 mcg of buprenorphine
Usual Dosage: See package insert for complete prescribing information.
Use entire film. Do not cut, tear, chew or swallow film.
Keep Belbuca out of sight and reach of children.
Children who accidentally take Belbuca will need emergency medical care.
℞ only


NDC 63481-820-01
Contains 1 Buccal Film
Belbuca™
(buprenorphine hydrochloride)
buccal film
750 mcg
Each buccal film contains: 750 mcg of buprenorphine
Usual Dosage: See package insert for complete prescribing information.
Use entire film. Do not cut, tear, chew or swallow film.
Keep Belbuca out of sight and reach of children.
Children who accidentally take Belbuca will need emergency medical care.
℞ only


NDC 63481-952-01
Contains 1 Buccal Film
Belbuca™
(buprenorphine hydrochloride)
buccal film
900 mcg
Each buccal film contains: 900 mcg of buprenorphine
Usual Dosage: See package insert for complete prescribing information.
Use entire film. Do not cut, tear, chew or swallow film.
Keep Belbuca out of sight and reach of children.
Children who accidentally take Belbuca will need emergency medical care.
℞ only

Indications

- Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate

- **Limitations of use:** reserve for use in patients for whom alternative treatment options are ineffective, not tolerated, or inadequate to provide sufficient management of pain; not indicated as an as-needed (prn) analgesic

Dosage & Administration

- See full labeling
- Apply against inside of cheek; do not chew or swallow
- **Opioid-naive:** initially 75mcg once daily or every 12 hours (if tolerated) for at least 4 days, then increase to 150mcg every 12 hours
- Individual titration should proceed in increments of 150mcg every 12 hours no sooner than every 4 days

Dosage & Administration

- **Max** 900mcg every 12 hours; consider alternate analgesic if inadequate
- **Conversion from other opioids:** see full labeling
- Use 600mcg, 750mcg, and 900mcg doses only following titration from lower doses of Belbuca
- **Severe hepatic impairment** or **oral mucositis:** reduce initial and titration doses by ½

Considerations for Special Populations

- **Pregnancy:** Potential neonatal opioid withdrawal syndrome during prolonged use
- **Labor & delivery, nursing mothers:** Not recommended
- **Pediatric:** Not established
- **Geriatric:** Use caution to ensure safe use
- **Hepatic impairment:** Moderate to severe impairment: not studied

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

Warnings/Precautions

- Abuse potential (monitor)
- Life-threatening respiratory depression; monitor within first 24–72 hours of initiating therapy and following dose increases
- Accidental exposure may cause fatal overdose (especially in children)
- COPD, cor pulmonale, decreased respiratory reserve, hypoxia, hypercapnia, or pre-existing respiratory depression; monitor and consider non-opioid analgesics
- History of long QT syndrome; avoid

Warnings/Precautions

- Hypokalemia, hypomagnesemia, unstable cardiac disease (eg, unstable atrial fibrillation, symptomatic bradycardia, unstable CHF, active myocardial ischemia); monitor ECG periodically
- Head injury
- Increased intracranial pressure, brain tumors; monitor
- Impaired consciousness, coma, circulatory shock; avoid
- Biliary tract dysfunction
- Acute pancreatitis

Warnings/Precautions

- Seizure disorders
- Known or suspected mucositis; monitor for toxicity
- Hepatotoxicity: obtain baseline LFTs in at-risk patients and monitor during treatment
- Avoid abrupt cessation
- Reevaluate periodically
- Drug abusers
- Elderly, cachectic, debilitated

Interactions

- May be potentiated by CYP3A4 inhibitors; if needed, monitor and consider dose adjustments
- May be antagonized by CYP3A4 inducers; monitor and consider dose adjustments
- Concomitant NNRTIs (eg, efavirenz, nevirapine, etravirine, delavirdine) or PIs (eg, atazanavir, ritonavir); monitor and adjust buprenorphine dose, if needed

Interactions

- Potentiation with alcohol or other CNS depressants (eg, sedatives, anxiolytics, hypnotics, neuroleptics, general anesthetics, other opioids); monitor and reduce doses
- Increased respiratory depression with concomitant benzodiazepines, muscle relaxants

Interactions

- Avoid concomitant Class IA or III antiarrhythmics or other drugs that prolong the QT interval
- Avoid concomitant butorphanol, nalbuphine, pentazocine
- May reduce efficacy of diuretics; monitor
- Paralytic ileus may occur with anticholinergics

Adverse Reactions

- Nausea
- Constipation
- Headache
- Vomiting
- Dizziness
- Somnolence
- Fatigue
- Hypersensitivity

Mechanism of Action

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

Pharmacokinetics

- **Distribution:** Approximately 96% protein bound
- **Metabolism:** N-dealkylation (CYP3A4) and glucuronidation
- **Elimination:** Fecal (major)

Clinical Trials

- The efficacy of Belbuca was evaluated in three 12-week double-blind, placebo-controlled trials in opioid-naive and opioid-experienced patients with moderate-to-severe chronic low back pain using pain scores as the primary efficacy variable

Clinical Trials

- Two of these studies demonstrated efficacy in patients with low back pain
- One study in low back pain did not show a statistically significant pain reduction for Belbuca vs. placebo

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the complete product monograph available at:

  http://www.empr.com/belbuca/drugproduct/402/