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#### Interactions with Benzodiazepines and Other CNS Depressants

Inform patients and caregivers that potentially fatal additive effects may occur if BELBUCA is used with benzodiazepines or other CNS depressants, including alcohol, and not to use these concomitantly unless supervised by a healthcare provider [see *Warnings and Precautions (5.5)*, *Drug Interactions (7)*].

#### Serotonin Syndrome

Inform patients that BELBUCA could cause a rare but potentially life-threatening condition resulting from concomitant administration of serotonergic drugs. Warn patients of the symptoms of serotonin syndrome and to seek medical attention right away if symptoms develop. Instruct patients to inform their physicians if they are taking, or plan to take, serotonergic medications [see *Drug Interactions (7)*].

#### Adrenal Insufficiency

Inform patients that BELBUCA could cause adrenal insufficiency, a potentially life-threatening condition. Adrenal insufficiency may present with non-specific symptoms and signs such as nausea, vomiting, anorexia, fatigue, weakness, dizziness, and low blood pressure. Advise patients to seek medical attention if they experience a constellation of these symptoms [see *Warnings and Precautions (5.7)*].

#### Interaction with Benzodiazepines

Warn patients that it is extremely dangerous to self-administer benzodiazepines while taking BELBUCA, and warn patients to use benzodiazepines concurrently with BELBUCA only as directed by their physician [see *Drug Interactions (7)*].

#### Important Administration Instructions

Instruct patients how to properly use BELBUCA, including the following:

- To carefully follow instructions for the application of BELBUCA and to avoid eating or drinking until it dissolves.
- To apply BELBUCA once daily, or every twelve (12) hours at the same time or times each day.
- To avoid applying BELBUCA to areas of the mouth with any open sores or lesions.
- To not use BELBUCA if the pouch seal is broken or the buccal film is cut, damaged, or changed in any way.

#### Important Discontinuation Instructions

In order to avoid developing withdrawal symptoms, instruct patients not to discontinue BELBUCA without first discussing a tapering plan with the prescriber [see *Dosage and Administration (2.5)*].

#### Hypotension

Inform patients that BELBUCA may cause orthostatic hypotension and syncope. Instruct patients how to recognize symptoms of low blood pressure and how to reduce the risk of serious consequences should hypotension occur (e.g., sit or lie down, carefully rise from a sitting or lying position) [see *Warnings and Precautions (5.9)*].

#### Anaphylaxis

Inform patients that anaphylaxis has been reported with ingredients contained in BELBUCA. Advise patients how to recognize such a reaction and when to seek medical attention [see *Warnings and Precautions (5.13)*].

#### Pregnancy

##### *Neonatal Opioid Withdrawal Syndrome*

Inform female patients of reproductive potential that prolonged use of BELBUCA during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated [see *Warnings and Precautions (5.4)*, *Use in Specific Populations (8.1)*].

#### *Embryofetal Toxicity*

Advise female patients that BELBUCA can cause fetal harm and to inform their healthcare provider of a known or suspected pregnancy [see *Use in Specific Populations (8.1)*].

#### Lactation

Advise patients that breastfeeding is not recommended during treatment with BELBUCA [see *Use in Specific Populations (8.2)*].

#### Constipation

Advise patients of the potential for severe constipation, including management instructions and when to seek medical attention [see *Adverse Reactions (6)*, *Clinical Pharmacology (12.2)*].

#### Driving or Operating Heavy Machinery

Inform patients that BELBUCA may impair the ability to perform potentially hazardous activities such as driving a car or operating heavy machinery. Advise patients not to perform such tasks until they know how they will react to the medication [see *Warnings and Precautions (5.18)*].

Healthcare professionals can telephone BioDelivery Sciences International, Inc. at 1-800-469-0261 or access [www.BELBUCA.com](http://www.BELBUCA.com) for information on this product.

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**Medication Guide**  
**BELBUCA® (bel-BUE-kuh)**  
**(buprenorphine buccal film), CIII**

**BELBUCA is:**

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage pain severe enough to require daily around-the-clock, long-term treatment with an opioid, when other pain treatments such as non-opioid pain medicines or immediate-release opioid medicines do not treat your pain well enough or you cannot tolerate them.
- A long-acting opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed, you are at risk for opioid addiction, abuse, and misuse that can lead to death.
- Not for use to treat pain that is not around-the-clock.

**Important information about BELBUCA:**

- **Get emergency help or call 911 right away if you take too much BELBUCA (overdose).** When you first start taking BELBUCA, when your dose is changed, or if you take too much (overdose), serious or life-threatening breathing problems that can lead to death may occur. Talk to your healthcare provider about naloxone, a medicine for the emergency treatment of an opioid overdose.
- Taking BELBUCA with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.
- Never give anyone else your BELBUCA. They could die from taking it. Selling or giving away BELBUCA is against the law.
- Store BELBUCA securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

**Do not use BELBUCA if you have:**

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.

**Before taking BELBUCA, tell your healthcare provider if you have a history of:**

- head injury, seizures
- liver, kidney, thyroid problems
- problems urinating
- heart rhythm problems (long QT syndrome)
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, opioid overdose, or mental health problems

**Tell your healthcare provider if you are:**

- **pregnant or planning to become pregnant.** Prolonged use of BELBUCA during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **breastfeeding.** Not recommended during treatment with BELBUCA. It may harm your baby.
- living in a household where there are small children or someone who has abused street or prescription drugs.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking BELBUCA with certain other medicines can cause serious side effects and could lead to death.











