

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 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.
- 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. Store BELBUCA away from children and in a safe place to prevent stealing or abuse. Selling or giving away BELBUCA is against the law.

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 applying 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, 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.
- 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.

While using BELBUCA:

- Do not change your dose. Apply BELBUCA exactly as prescribed by your healthcare provider. Use the lowest effective dose possible for the shortest time needed.
- See the detailed Instructions for Use for information about how to apply BELBUCA.
- Do not apply BELBUCA if the package seal is broken or the film is cut, damaged, or changed in any way.
- After the film has adhered to your cheek, avoid eating or drinking until the film has completely dissolved, usually within 30 minutes.
- Avoid touching or moving the buccal film with your tongue or fingers.
- **Do not chew, swallow, snort or inject BELBUCA. This will result in uncontrolled delivery of buprenorphine and may cause you to overdose and die.**
- **Call your healthcare provider if the dose you are using does not control your pain.**
- **Do not stop using BELBUCA without talking to your healthcare provider.**
- After you stop using BELBUCA, remove any unused film from the foil pack and flush down the toilet. Throw the empty foil packaging in the trash.

While using BELBUCA DO NOT:

- Drive or operate heavy machinery, until you know how BELBUCA affects you. BELBUCA can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines containing alcohol. Using products containing alcohol during treatment with BELBUCA may cause you to overdose and die.

The possible side effects of BELBUCA are:

- nausea, constipation, headache, vomiting, dizziness, and sleepiness. Call your healthcare provider if you have any of these symptoms and they are severe.

Get emergency medical help if you have:

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue or throat, extreme drowsiness, light-headedness when changing positions, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, or mental changes such as confusion.

These are not all the possible side effects of BELBUCA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to dailymed.nlm.nih.gov**

Manufactured for: BioDelivery Sciences International, Inc., Raleigh, NC 27612, or call 1-800-469-0261.

Instructions for Use

BELBUCA (bel-BUE-kuh) (buprenorphine) buccal film, CIII

Before you use BELBUCA buccal film, it is important that you read the Medication Guide and these Patient Instructions for Use so that you use BELBUCA the right way. Ask your healthcare provider or pharmacist if you have any questions about the right way to use BELBUCA.

Important:

- BELBUCA buccal film is sealed in a foil package. **Do not open the package until ready to use.** After opening, use the entire BELBUCA buccal film right away.
- Do not apply BELBUCA buccal film if the package seal is broken or the film is cut, damaged, or changed in any way.
- BELBUCA buccal film is available in different strengths. Make sure you have the strength that has been prescribed for you.
- Avoid placing BELBUCA buccal film to areas of the mouth with any open sores or lesions.

Open the BELBUCA package:

- Hold the foil package as shown below (see **Figure A**). Fold along the dotted line at the top of the foil package.



Figure A

- Keep folded and tear down or cut with scissors at the notch in the direction of the scissors on the dotted line (See **Figure B**). Tear all the way to the bottom. Be careful to avoid cutting and damaging the BELBUCA buccal film when using scissors.



Figure B

- Remove BELBUCA film from the foil package (see **Figure C**).



Figure C

Use BELBUCA buccal film as follows:

1. Use your tongue to wet the inside of your cheek or rinse your mouth with water to moisten the area in your mouth before you place BELBUCA.
2. Hold the BELBUCA buccal film with clean, dry fingers with the yellow side facing up (see **Figure D**).



Figure D

3. Using a finger, place the yellow side of the BELBUCA buccal film against the inside of your moistened cheek. Press and hold the BELBUCA buccal film in place for 5 seconds and then take your finger away (see **Figure E**).

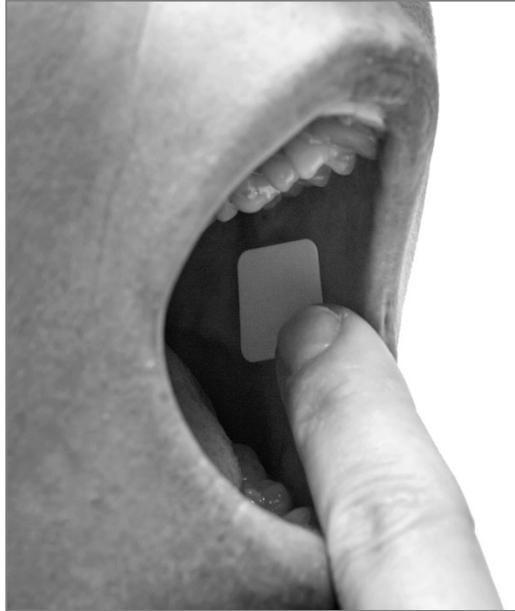


Figure E

4. The BELBUCA buccal film will stick to the inside of your cheek (see **Figure F**).



Figure F

5. Leave the BELBUCA buccal film in place until it has completely dissolved, usually within 30 minutes after you apply it.
 - **Avoid eating food or drinking liquids until BELBUCA buccal film has dissolved.**
 - **Avoid touching or moving BELBUCA buccal film with your tongue or finger after it is in place.**
 - **Do not chew or swallow BELBUCA.**

This Instruction for Use has been approved by the U.S. Food and Drug Administration.

For more information call BioDelivery Sciences International, Inc. at 1-800-469-0261.

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Raleigh, NC 27612

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