FREQUENTLY ASKED QUESTIONS ABOUT BELBUCA®

BELBUCA®
(buprenorphine buccal film)
75 • 150 • 300 • 450 • 600 • 750 • 900 mcg
Get Back to Life

What is chronic pain?

Chronic pain is pain that lasts longer than 6 months. It can be mild or severe. When chronic pain is severe, it can impact daily activities, sleep, even relationships and work.

How do you treat or manage chronic pain?

Chronic pain treatment is not as simple as finding a one-size-fits-all solution. There are many treatments to help chronic pain. You and your healthcare provider will work together to determine what works best for you. The goal of treating chronic pain is the same as with any disease—to help you find relief and get back to doing the things you enjoy.

Why consider a long-acting opioid?

You and your healthcare provider may decide you need to move beyond your current treatment if your medications or therapies are not reducing your pain level enough, you are losing sleep because of pain, you are frequently using a short-acting opioid, or you need around-the-clock treatment.

What is BELBUCA?

BELBUCA (buprenorphine buccal film) 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.

What is buprenorphine?

BELBUCA contains a medication called buprenorphine. Buprenorphine is a long-acting opioid that stays in your system longer than short-acting opioids. This means BELBUCA can be taken every 12 hours, instead of every 4 to 6 hours like many short-acting opioids.

What side effects does BELBUCA cause?

Until your body adjusts to treatment, you may experience side effects like nausea, constipation, headache, vomiting, dizziness, or sleepiness. Your healthcare provider may adjust your dose to provide pain relief or to help minimize any side effects. Do not change your dose or stop taking BELBUCA without talking to your healthcare provider.

Why is BELBUCA a buccal film?

The BELBUCA buccal film technology helps the medicine, buprenorphine, get into your body more efficiently than when it is swallowed. When swallowed, buprenorphine is significantly less effective at treating your pain.

How do I know if I am taking the right dose or strength of BELBUCA?

BELBUCA has 7 dose strengths that will help you and your healthcare provider find your optimal dose. An optimal dose is the amount that provides the relief you need while minimizing side effects. It may take a few adjustments to find your optimal dose, so remember to talk to your doctor frequently.

Please see Important Safety Information, including Boxed Warning, on following pages.

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How do I apply BELBUCA?

Before you begin, make sure the inside of your mouth is moist, either by using your tongue or by rinsing your mouth with water. Be sure your fingers are clean and dry. To apply BELBUCA, just **peel**, **place**, and **press**.



1. Peel and tear open the package to carefully remove the film.



2. Place the film on your finger.



3. Press the yellow side against the inside of your cheek.

It may take a few times to get accustomed to using BELBUCA. Visit BELBUCA.com to watch a step-by-step instructional video on proper application technique.

Where is the right place to put BELBUCA inside my cheek?

BELBUCA should be applied to the middle of the inside of your cheek. Do not place the film too high or too far back on your cheek. Avoid applying the film to areas of your mouth with any open sores or lesions.

Can I eat, drink, or talk when the buccal film is in my mouth?

Do not eat or drink until the buccal film has completely dissolved. After applying BELBUCA, you can speak and swallow normally while the film is dissolving, usually within 30 minutes—just do not do anything that would move the buccal film in your mouth.

What does it feel like when the film starts to dissolve?

While BELBUCA is adhered to the inside of your cheek, you may taste a mild peppermint flavor. As it dissolves, it is normal for the texture of the film to change.

How long does it take to dissolve?

BELBUCA works by sticking to the inside of your cheek and then dissolving completely—usually within 30 minutes. Leave BELBUCA on the inside of your cheek until fully dissolved. If you chew or swallow the buccal film, it may not be as effective or may cause choking, overdose, or death. As such, be careful not to chew or swallow the film.

How much does BELBUCA cost?

The cost of BELBUCA varies based on your insurance plan. BELBUCA offers copay assistance to eligible patients and is dedicated to helping patients access the medication they need. In the 1st month, eligible patients pay as little as $0 up front and save up to $100 off their copay per prescription, for up to 3 prescriptions. In the 2nd month, patients pay as little as $25 up front and save up to $75 off their remaining copay per prescription, for up to 3 prescriptions. In the 3rd-12th months, patients pay as little as $25 up front and save up to $75 off their remaining copay per prescription, for only 1 prescription per month. Restrictions apply. Please see eligibility criteria on the back of the card.

Please see Important Safety Information, including Boxed Warning, on following pages.

IMPORTANT SAFETY INFORMATION

BELBUCA (buprenorphine buccal film) 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 SAFETY INFORMATION about BELBUCA®

WARNING: ADDICTION, ABUSE, AND MISUSE; RISK EVALUATION AND MITIGATION STRATEGY (REMS); LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL EXPOSURE; NEONATAL OPIOID WITHDRAWAL SYNDROME; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES AND OTHER CNS DEPRESSANTS

Addiction, Abuse, and Misuse

BELBUCA exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing BELBUCA, and monitor regularly for these behaviors and conditions.

Risk Evaluation and Mitigation Strategy (REMS)

To ensure that the benefits of opioid analgesics outweigh the risks of addiction, abuse, and misuse, the FDA has required a REMS for these products. Under the requirements of the REMS, drug companies with approved opioid analgesic products must make REMS-compliant education programs available to healthcare providers. Healthcare providers are strongly encouraged to

- **complete a REMS-compliant education program,**
- **counsel patients and/or their caregivers, with every prescription, on safe use, serious risks, storage, and disposal of these products,**
- **emphasize to patients and their caregivers the importance of reading the Medication Guide every time it is provided by their pharmacist, and**
- **consider other tools to improve patient, household, and community safety.**

Life-Threatening Respiratory Depression

Serious, life-threatening, or fatal respiratory depression may occur with use of BELBUCA. Monitor for respiratory depression, especially during initiation of BELBUCA or following a dose increase. Misuse or abuse of BELBUCA by chewing, swallowing, snorting, or injecting buprenorphine extracted from the buccal film will result in the uncontrolled delivery of buprenorphine and poses a significant risk of overdose and death.

Accidental Exposure

Accidental exposure to even one dose of BELBUCA, especially in children, can result in a fatal overdose of buprenorphine.

Neonatal Opioid Withdrawal Syndrome

Prolonged use of BELBUCA during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated. If prolonged opioid use is required in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

Risks from Concomitant Use with Benzodiazepines Or Other CNS Depressants

Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for use in patients for whom alternative treatment options are inadequate; limit dosages and durations to the minimum required; and follow patients for signs and symptoms of respiratory depression and sedation.

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. Selling or giving away BELBUCA is against the law.

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IMPORTANT SAFETY INFORMATION (cont)

- 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 applying BELBUCA, tell your healthcare provider if you have a history of:

- head injury, seizures
- heart rhythm problems (long QT syndrome)
- liver, kidney, thyroid problems
- pancreas or gallbladder problems
- problems urinating
- 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.

When taking 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.**
- Dispose of expired, unwanted, or unused BELBUCA by removing the BELBUCA film from the foil packaging, and promptly flushing down the toilet (if a drug takeback option is not readily available).
  Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

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**

Please see full Prescribing Information, including Boxed Warning, and Medication Guide, or speak to your healthcare provider if you have questions about BELBUCA.

Manufactured for: BioDelivery Sciences International, Inc.

biodelivery SCIENCES

Rx Only

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