

How to Apply **BELBUCA**®

You have taken a step toward chronic pain* relief by choosing BELBUCA. Make sure you get started on the right foot by reading the instructions for use and practicing applying the BELBUCA film.

***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.

**Please see Important Safety Information, including Boxed Warning, on back.
Please see full Prescribing Information and Medication Guide inside the toolkit.**

Easy as 1-2-3



BELBUCA is a small, thin, square film.

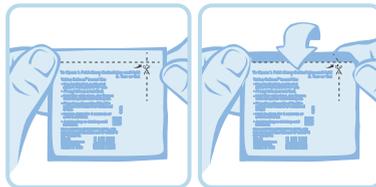
It works by sticking to the inside of your cheek and dissolving completely.

This allows the medicine, buprenorphine, to get into your body more efficiently than when swallowed.

1. PEEL

- Make sure your fingers are clean and dry
- Hold the foil package as shown (Figure A)
- Fold along the dotted line at the top of the package

Figure A



TIP: Do not open the sealed foil packet until you are ready to apply BELBUCA.

- Tear open the individually sealed foil package by folding and tearing along the dotted line (Figure B)

Figure B



- You can also use scissors to cut along the dotted line (if you use scissors, be careful to avoid cutting or damaging the buccal film)

- Carefully remove the film from the package (Figure C)

Figure C



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.

2. PLACE

- Ensure that the inside of your cheek—where the film will be placed—is wet (you can wet the inside of your cheek by using your tongue or rinsing your mouth with water)

Figure D



- Place the film on your fingertips with the yellow side facing up (Figure D)

TIP: Do not apply BELBUCA to areas of the mouth with any open sores or lesions.

Important information about BELBUCA (cont):

- 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.

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3. PRESS

- Press the yellow side of the BELBUCA film against the inside of your cheek. Hold in place for 5 seconds and then take your finger away (Figure E)

Figure E



TIP: It may help to press another finger on the outside of your cheek to position the film correctly.

- Leave BELBUCA on the inside of your cheek until it is fully dissolved—usually within 30 minutes (Figure F)

Figure F



- Avoid touching or moving the buccal film with your tongue or fingers
- Remember, once the film has adhered to your cheek, you cannot eat or drink until the film is completely dissolved, usually within 30 minutes. You can, however, talk and swallow while the film is in your mouth

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- 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 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 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.
- 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.

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 or call 911 right away 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.

YOU MAY EXPERIENCE AN ADJUSTMENT PERIOD WHEN YOU START BELBUCA®

Give your body time to adjust

You may experience a change in symptoms when you start BELBUCA. You might need time to reach your optimal dose to make sure you get adequate chronic pain relief to help minimize side effects.

Track your progress

Keep a record of your pain, symptoms, and any side effects. Record exactly what you're feeling to make the discussion with your doctor easier.

Report any changes

Tell your healthcare provider if you experience any changes to your symptoms, and report any side effects to your provider immediately. Never attempt to manage or deal with side effects on your own.

Start tracking your progress by using the Treatment Tracker found at www.Belbuca.com/resources



WATCH A
"HOW TO APPLY
BELBUCA" VIDEO

Visit www.Belbuca.com/starting-treatment, where you can watch a brief video showing how to properly apply BELBUCA buccal film.



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Rx Only

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BEL-0196b.1/April 2021 1-800-469-0261


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

Get Back to Life