



# BELBUCA

## CAN HELP YOU FIND RELIEF FROM YOUR SEVERE AND PERSISTENT PAIN\*

BELBUCA® (buprenorphine) is a long-acting opioid to manage severe and persistent pain when other treatment options are inadequate

For potential savings, visit [belbuca.com/savings](https://belbuca.com/savings).

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

### \*APPROVED USE

**BELBUCA**® (buprenorphine buccal film) CIII is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage severe and persistent pain that requires an extended treatment period with a daily opioid pain medicine when other pain 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 to be taken on an “as needed” basis.

### IMPORTANT SAFETY INFORMATION about BELBUCA®

#### WARNING: SERIOUS AND LIFE-THREATENING RISKS FROM USE OF BELBUCA

##### 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.

##### Life-Threatening Respiratory Depression

Serious, life-threatening, or fatal respiratory depression may occur with use of BELBUCA, especially during initiation or following a dosage increase. To reduce the risk of respiratory depression, proper dosing and titration of BELBUCA are essential. 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.

##### 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 of BELBUCA and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate.

##### Neonatal Opioid Withdrawal Syndrome (NOWS)

If opioid use is required for an extended period of time in a pregnant woman, advise the patient of the risk of NOWS, which may be life-threatening if not recognized and treated. Ensure that management by neonatology experts will be available at delivery.

##### Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS)

Healthcare providers are strongly encouraged to complete a REMS-compliant education program and to counsel patients and caregivers on serious risks, safe use, and the importance of reading the Medication Guide with each prescription.

Please see full Prescribing Information, including Boxed Warning on Addiction, Abuse, and Misuse, and other serious risks, and Medication Guide at [belbuca.com/PI](https://belbuca.com/PI).

Speak to your healthcare provider if you have questions about BELBUCA.

# WHY HAS **BELBUCA** BEEN PRESCRIBED FOR ME?

BELBUCA is a long-acting opioid that may be used when:



Your pain causes nighttime awakenings



Your current treatment could require multiple daily doses of medicine



Your pain requires around-the-clock relief



Your current treatment causes tolerability issues and/or side effects



**BELBUCA is a strong prescription pain medicine (buprenorphine).**

BELBUCA contains an opioid (narcotic) that is used to manage severe and persistent pain that requires an extended treatment period with a daily opioid pain medicine. BELBUCA is used when other pain medicines do not treat your pain well enough or you cannot tolerate them.

## **IMPORTANT SAFETY INFORMATION** about BELBUCA®

### **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.

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- 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.



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# HOW IS **BELBUCA** DIFFERENT?

**BELBUCA is the first and only schedule III opioid using buprenorphine buccal film technology**



## **BELBUCA is a long-acting opioid.**

BELBUCA works over an extended period of time, which means it stays in your system longer than short-acting opioids. BELBUCA will be taken every 12 hours, instead of every 4 to 6 hours like many short-acting opioids.

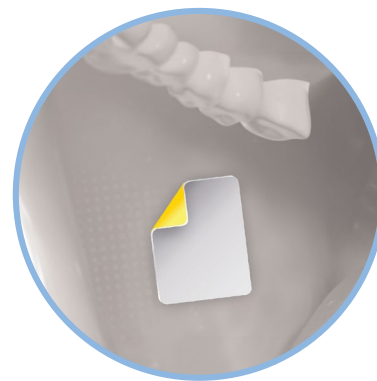
**There is no clinical data comparing BELBUCA with any other pain medication.**

## **IMPORTANT SAFETY INFORMATION about BELBUCA® (cont'd)**

**Before taking 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
- tooth problems, including a history of cavities
- abuse of street or prescription drugs, alcohol addiction, opioid overdose, or mental health problems

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For illustrative purposes only. Not the actual product or size.

## **BELBUCA uses a different delivery system.**

BELBUCA is a thin, square film that you put in your mouth and press against the inside of your cheek. The film delivers the medicine, buprenorphine, efficiently through the inside of your cheek, entering your bloodstream more directly.



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# WHAT CAN I EXPECT FROM BELBUCA THERAPY?



BELBUCA has been proven to reduce severe and persistent pain.

- In people previously taking commonly prescribed opioids
- In people who have not taken opioids



The possible side effects of BELBUCA include nausea, constipation, headache, vomiting, dizziness, and sleepiness.\*

- Call your healthcare provider if you have any of these symptoms and they are severe



BELBUCA has 7 dosage strengths and is taken 2 times a day.

- Your healthcare provider will be able to determine the appropriate/optimal dose to help you manage your severe and persistent pain

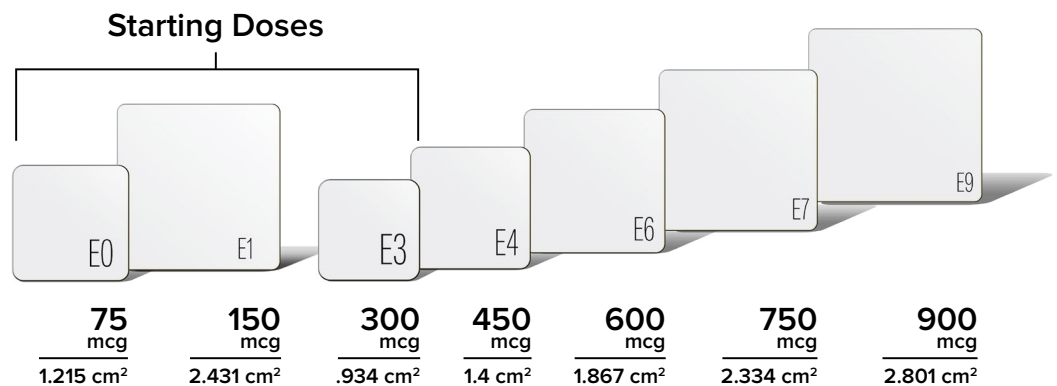
## AS YOU BEGIN TREATMENT



BELBUCA OFFERS 7 DOSAGE STRENGTHS



*It is important to know that your starting dose may not be the final dose* you need to optimally manage your severe and persistent pain. It may take time for you and your doctor to find the optimal dose for you.



Films are not actual size. Maximum dose is 900 mcg every 12 hours.

\*Results from clinical studies compared with placebo (sugar pill). Individual results may vary.

### IMPORTANT SAFETY INFORMATION about BELBUCA® (cont'd)

Tell your healthcare provider if you are:

- **noticing your pain getting worse.** If your pain gets worse after you take BELBUCA, do not take more of BELBUCA without first talking to your healthcare provider. Talk to your healthcare provider if the pain that you have increases, if you feel more sensitive to pain, or if you have new pain after taking BELBUCA.
- **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.

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# TAKING BELBUCA

Make sure you apply the film at the same times each day, following your healthcare provider's instructions

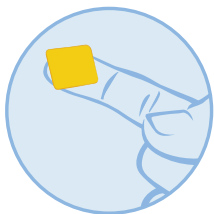
Before you begin, wet the inside of your cheek with your tongue or with water.

## 1. PEEL OPEN PACKAGE



- With clean, dry fingers, peel open the foil package. Fold along the dotted line at the top of the package, and tear at the perforation
- You can also use scissors to carefully cut along the dotted line

## 2. PLACE ON FINGER



- Carefully remove the BELBUCA film from the foil package
- Place the film on your dry finger with the yellow side facing up

- 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

## IMPORTANT SAFETY INFORMATION about BELBUCA® (cont'd)

Tell your healthcare provider if you are (cont'd):

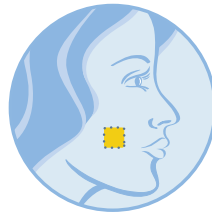
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking BELBUCA with certain other medicines can cause serious side effects and could lead to death.

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.

Please see full Prescribing Information, including Boxed Warning on Addiction, Abuse, and Misuse, and other serious risks, and Medication Guide at [belbuca.com/PI](http://belbuca.com/PI). Speak to your healthcare provider if you have questions about BELBUCA.

## 3. PRESS INSIDE OF CHEEK



- Press the yellow side against the **inside of your cheek**. Hold it in place for 5 seconds, and then remove your finger
- Leave BELBUCA on the inside of your cheek until fully dissolved, usually within 30 minutes
- After BELBUCA is completely dissolved, rinse your mouth with water, and swallow. Wait at least one hour before brushing your teeth

## LEARN MORE

about applying BELBUCA by viewing the **application video** at [belbuca.com/resources](http://belbuca.com/resources)



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# LISTEN, TRACK, AND TALK

## Be patient, and give your body time.

You may experience a change in symptoms. It may take time and a few adjustments for you and your healthcare provider to find your optimal dose.

## Track your progress.

Keep a record of your pain, symptoms, and side effects. Discuss these issues with your healthcare provider.

## Report any changes.

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

## NOTES:

Use this space to record your treatment progress, topics for discussion with your doctor, side effects...or anything, really.

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## IMPORTANT SAFETY INFORMATION about BELBUCA®

### 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
- heart rhythm problems (long QT syndrome)
- liver, kidney, thyroid problems
- pancreas or gallbladder problems
- problems urinating
- tooth problems, including a history of cavities
- abuse of street or prescription drugs, alcohol addiction, opioid overdose, or mental health problems

### Tell your healthcare provider if you are:

- **noticing your pain getting worse.** If your pain gets worse after you take BELBUCA, do not take more of BELBUCA without first talking to your healthcare provider. Talk to your healthcare provider if the pain that you have increases, if you feel more sensitive to pain, or if you have new pain after taking BELBUCA.
- **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.
- After BELBUCA is completely dissolved, rinse your mouth with water and swallow. Wait for at least one hour before brushing teeth.
- Report any problems with your teeth immediately to your healthcare provider and schedule an appointment with a dentist. Tell your dentist that you have started taking BELBUCA.
- 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](http://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 healthcare provider 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](http://dailymed.nlm.nih.gov).

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COMMERCIALLY INSURED PATIENTS  
MAY PAY AS LITTLE AS \$0  
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*Present your downloaded copay card to your pharmacist with your BELBUCA prescription.*

**\*Eligibility Criteria**

This offer is valid for the purchase of BELBUCA manufactured for Collegium Pharmaceutical, Inc. and lawfully purchased from an authorized retailer or distributor in the United States or its territories. This offer is not insurance and is not valid for mail order or prescriptions purchased under Medicaid, Medicare, TRICARE, or similar federal or state programs, or for patients who are Medicare eligible and enrolled in an employer-sponsored group waiver health plan or government-subsidized prescription drug benefit program for retirees. Offer not valid where prohibited by law, taxed, or restricted. Your offer has its own unique ID number. This offer is not transferable, is limited to one per person, and may not be combined with any other offer. Offer must be presented along with a valid prescription for BELBUCA at the time of purchase. If you lose your card before the first time you use it, simply print or download a new copy at BELBUCA.com and bring it to the pharmacy. Cash Discount Cards and other non-insurance plans are not valid as primary under this offer. If the patient is eligible for drug benefits under any such program, the patient cannot use this offer. By using this offer, the patient certifies that he or she will comply with any terms of his or her health insurance contract requiring notification to his or her payer of the existence and/or value of this offer. This offer is not valid for cash paying patients and/or patients under 18 years of age.

Collegium Pharmaceutical, Inc. reserves the right to change or discontinue this offer at any time without notice.

ACCESS YOUR DOWNLOADABLE COPAY CARD AT  
**BELBUCA.COM**  
FOR POTENTIAL SAVINGS

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PP-BEL-US-0211 06/24