TREATMENT TRACKER

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

On track toward chronic pain relief

You have taken a step toward chronic pain relief by choosing BELBUCA®. As you begin treatment, it is important to know that your starting dose may not be the final one you need to optimally manage your chronic pain. BELBUCA has 7 dosing options, and it may take time to get to the right, or optimal, dose.

Your optimal dose should provide the relief you need while minimizing side effects. In clinical trials, 84% of patients found their optimal dose to be between 450 mcg and 900 mcg twice daily.

Listen to your body and observe how you are feeling. Then, share your progress with your doctor and work together to find your optimal dose.

Why is tracking your progress important?

Everyone's pain is unique, and it may take time to find your optimal dose when starting a new chronic pain medication like BELBUCA. How long it will take, and which doses are required, will depend upon your chronic pain's response to BELBUCA and your doctor's instruction.

In clinical trials, once a patient reached their optimal dose, 86% were able to stay on that dose without making any changes to their treatment for the duration of the 48-week study (almost a year).

1 Capture your start with BELBUCA. Answer the initial questions below.

How do/did you feel about starting BELBUCA? Check all that apply.

☐ Hopeful ☐ Positive ☐ Indifferent ☐ Anxious ☐ Stressed

What are your treatment goals or aspirations?

Remember: BELBUCA is a long-acting opioid. It may take some time to feel the full effect of the medication, unlike short-acting opioids, which may have more immediate effects.

2 Print or download.

Print multiple copies of **"Tracking My BELBUCA Treatment"** (page 2) and complete one for each change in dose strength.

OR

Complete them electronically by saving a new copy of this pdf each time your dose strength changes. Be sure to save it (File > Save As) as a different file name.

E.g., "Tracking_My_BELBUCA_Treatment_MMDDYY.pdf."

3 Track and share.

- For each of your prescribed dosing strengths of BELBUCA, complete **"Tracking My BELBUCA Treatment"** (page 2).
- Share your answers with your doctor at your next visit.

TIP: Record exactly what you are feeling and when. Keep a notepad handy or make a note on your phone. Refer back to your notes as you complete **"Tracking My BELBUCA Treatment"** (page 2).

TRACKING MY BELBUCA TREATMENT

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Dose strength (check one)

Date: ____ / ____ / ____
Month Day Year

☐ 75 mcg ☐ 150 mcg ☐ 300 mcg ☐ 450 mcg ☐ 600 mcg ☐ 750 mcg ☐ 900 mcg

Your Other Pain Medications (e.g., over-the-counter, muscle relaxants, antidepressants, and short-acting opioids)

Name	Dose strength	How often?
_____	_____	_____ times per day
_____	_____	_____ times per day
_____	_____	_____ times per day

For the entries below, think about your overall experience on the above strength of BELBUCA.

Average level of pain

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No pain **Extreme pain**

Activities able to participate in

☐ Walking ☐ Driving ☐ Household chores ☐ Cooking ☐ Working ☐ Social activities

☐ Other _____

Waking up during the night

☐ Never ☐ Rarely ☐ Some nights ☐ Most nights ☐ Always

Restless sleep/Awoke tired

☐ Never ☐ Rarely ☐ Some nights ☐ Most nights ☐ Always

Overall mood level

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

Cheerful and calm **Depressed or anxious**

Side effects

☐ Nausea ☐ Constipation ☐ Headache ☐ Vomiting ☐ Dizziness ☐ Sleepiness

☐ Other _____

Reminder: It is important to continually share your progress with your doctor. There is no one-size-fits-all for getting to the right, or optimal, dose of BELBUCA. Share your treatment tracker at each follow-up visit to help maintain an open dialogue with your doctor that will help you get to the optimal dose of BELBUCA for you.

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
Manufactured for: BioDelivery Sciences International, Inc.

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

biodelivery SCIENCES

Rx Only

BEL-0172.1 / May 2020 BELBUCA.com 1-800-469-0261

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