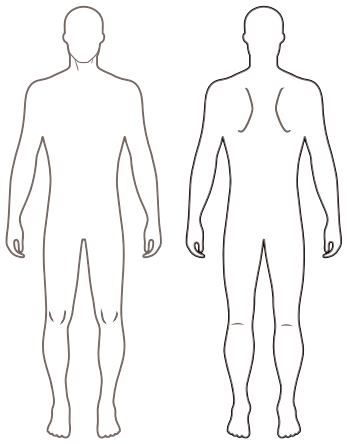
BELBUCA®
(buprenorphine) Buccal Film
75 • 150 • 300 • 450 • 600 • 750 • 900 mcg
A Responsible Choice

Doctor Discussion Guide

Getting the pain relief you need to stay active is important. Keeping track of your symptoms can help you and your healthcare provider determine if there is a need to adjust your medications.

Use this guide to prepare for your next visit with your healthcare provider. It can help you discuss how to manage your pain and achieve your goals. Bring it with you to your next healthcare provider visit to make the most of your appointment and to get back on track to feeling like yourself.

The primary source of my chronic pain is:



FRONT BACK

Circle the number that best describes your *pain on average* in the past week.

0 1 2 3 4 5 6 7 8 9 10

No pain

Pain as bad as you can imagine

Circle the number that best describes how, during the past week, pain has interfered with your *enjoyment of life*.

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

Circle the number that best describes how, during the past week, pain has interfered with your *general activity*.

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

My pain affects my ability to perform daily activities. (Check one.)

❑ Yes ❑ No

If you answered yes, which activities does your pain affect? (Circle any that apply.)

Sitting	Sleeping	Household chores	Other: _____
Standing	Driving	Gardening	_____
Walking	Cooking	Work	_____
		Social activities	_____

Think about how your pain affects your sleep. (Circle your response.)

My pain affects my ability to fall asleep

Always Most nights Some nights Rarely Never

I wake up in pain during the night

Always Most nights Some nights Rarely Never

I can sleep through the night without pain

Always Most nights Some nights Rarely Never

I am currently taking these medications to treat my chronic pain:

	Name	Dose/Strength	Frequency
Medication 1			
Medication 2			
Medication 3			
Medication 4			

I am using these non-medication therapies to try to control my chronic pain:

I am using these non-medication therapies to try to control my chronic pain:

My hope(s)/goal(s) for my pain management (medication and non-medication therapies):

I am experiencing the following symptoms as a result of my current pain therapies. (Check all that apply.)

- ❑ Addiction
- ❑ Appetite decrease
- ❑ Breathing difficulty
- ❑ Cloudy thinking
- ❑ Confusion
- ❑ Constipation
- ❑ Depression
- ❑ Dizziness
- ❑ Drowsiness
- ❑ Dry mouth
- ❑ Fatigue
- ❑ Headache
- ❑ Heart irregularities
- ❑ Indigestion
- ❑ Insomnia
- ❑ Itchiness
- ❑ Nausea and vomiting
- ❑ Nightmares
- ❑ Osteoporosis
- ❑ Rash
- ❑ Sexual dysfunction
- ❑ Sweating

Questions/Concerns

List any questions/concerns you have about your current pain treatment, such as treatment goals, addiction, or side effects. Bring them to your next appointment to discuss with your doctor.

My current pain therapy is not effectively controlling my pain. I would like to discuss other options.

Notes (Use this space to make notes during your appointment.)

Brought to you by BELBUCA®, a CIII long-acting opioid for the treatment of chronic pain.

September 2018 BELBUCA.com 1-800-469-0261

Please see Important Safety Information on following pages.

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INDICATION

BELBUCA® (buprenorphine) buccal film is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with long-acting opioid formulations, reserve BELBUCA® for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- BELBUCA® is not indicated as an as-needed (prn) analgesic.

IMPORTANT SAFETY INFORMATION about BELBUCA®

WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL EXPOSURE; AND NEONATAL OPIOID WITHDRAWAL SYNDROME; AND RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR 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 patients regularly for the development of these behaviors and conditions.

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 pose a significant risk of overdose and death.

Accidental Exposure

Accidental exposure to even one dose of BELBUCA®, especially by 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 and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period 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.

CONTRAINDICATIONS

BELBUCA® is contraindicated in patients with significant respiratory depression; acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment; known or suspected gastrointestinal obstruction, including paralytic ileus; and hypersensitivity (e.g., anaphylaxis) to buprenorphine.

WARNINGS AND PRECAUTIONS

Addiction, Abuse, and Misuse

- BELBUCA® contains buprenorphine, a Schedule III controlled substance. As an opioid, BELBUCA® exposes users to the risks of addiction, abuse, and misuse. Although the risk of addiction in any individual is unknown, it can occur in patients appropriately prescribed BELBUCA® and in those who obtain the drug illicitly. Addiction can occur at recommended doses and if the drug is misused or abused.
- Assess each patient's risk for opioid addiction, abuse, or misuse prior to prescribing BELBUCA® and monitor all patients receiving BELBUCA® for the development of these behaviors and conditions. Risks are increased in patients with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (e.g., major depression). The potential for these risks should not, however, prevent the proper management of pain in any given patient. Patients at increased risk may be prescribed opioids such as BELBUCA®, but use in such patients necessitates intensive counseling about the risks and proper use of BELBUCA®, along with intensive monitoring for signs of addiction, abuse, or misuse.
- Abuse or misuse of BELBUCA® by swallowing may cause choking, overdose, and death.
- Opioids are sought by drug abusers and people with addiction disorders and are subject to criminal diversion. Consider these risks when prescribing or dispensing BELBUCA®. Strategies to reduce the risk include prescribing the drug in the smallest appropriate quantity and advising the patient on the proper disposal of unused drug.

Life-Threatening Respiratory Depression

- Serious, life-threatening, or fatal respiratory depression has been reported with the use of opioids, even when used as recommended. Respiratory depression, if not immediately recognized and treated, may lead to respiratory arrest and death.
- While serious, life-threatening or fatal respiratory depression can occur at any time during the use of BELBUCA®; the risk is greatest during initiation of therapy or following a dosage increase. Monitor patients closely for respiratory depression when initiating therapy with BELBUCA® and following dosage increases.
- To reduce the risk of respiratory depression, proper dosing and titration of BELBUCA® are essential. Overestimating the dose of BELBUCA® when converting patients from another opioid product may result in fatal overdose with the first dose.

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- Accidental exposure to BELBUCA®, especially in children, can result in respiratory depression and death due to an overdose of buprenorphine.

Neonatal Opioid Withdrawal Syndrome

- Prolonged use of BELBUCA® during pregnancy can result in withdrawal in the neonate. Neonatal opioid withdrawal syndrome, unlike opioid withdrawal syndrome in adults, may be life threatening if not recognized and treated and requires management according to protocols developed by neonatology experts. Observe newborns for signs of neonatal opioid withdrawal syndrome and manage accordingly. Advise pregnant women using opioids for a prolonged period of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

Risks due to Interactions with Benzodiazepines or Other Central Nervous System Depressants

- Profound sedation, respiratory depression, coma, and death may result from the concomitant use of BELBUCA® with benzodiazepines or other CNS depressants (e.g., non-benzodiazepine sedatives/hypnotics, anxiolytics, tranquilizers, muscle relaxants, general anesthetics, antipsychotics, other opioids, alcohol). Because of these risks, reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate.

  If the decision is made to prescribe a benzodiazepine or other CNS depressant concomitantly with an opioid analgesic, prescribe the lowest effective dosages and minimum durations of concomitant use. Follow patients closely for signs and symptoms of respiratory depression and sedation.

Risk of Life-Threatening Respiratory Depression in Patients with Chronic Pulmonary Disease or in Elderly, Cachectic, or Debilitated Patients

- The use of BELBUCA® in patients with acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment is contraindicated.
- Patients with Chronic Pulmonary Disease: BELBUCA®-treated patients with significant chronic obstructive pulmonary disease or cor pulmonale and those with substantially decreased respiratory reserve, hypoxia, hypercapnia, or pre-existing respiratory depression are at increased risk of decreased respiratory drive, including apnea, even at recommended dosages of BELBUCA®.
- Life-threatening respiratory depression is more likely to occur in elderly, cachectic, or debilitated patients as they may have altered pharmacokinetics or altered clearance compared with younger, healthier patients.
- Monitor such patients closely, particularly when initiating and titrating BELBUCA® and when BELBUCA® is given concomitantly with other drugs that depress respiration.

Adrenal Insufficiency

- Cases of adrenal insufficiency have been reported with opioid use, more often following greater than one month of use. Presentation of adrenal insufficiency may include non-specific symptoms and signs including nausea, vomiting, anorexia, fatigue, weakness, dizziness, and low blood pressure. If adrenal insufficiency is suspected, confirm the diagnosis with diagnostic testing as soon as possible. If adrenal insufficiency is diagnosed, treat with physiologic replacement doses of corticosteroids. Wean the patient off of the opioid to allow adrenal function to recover and continue corticosteroid treatment until adrenal function recovers. Other opioids may be tried as some cases reported use of a different opioid without recurrence of adrenal insufficiency. The information available does not identify any particular opioids as being more likely to be associated with adrenal insufficiency.

QTc Prolongation

- BELBUCA® has been observed to prolong the QTc interval in some subjects participating in clinical trials. Consider these observations in clinical decisions when prescribing BELBUCA® to patients with hypokalemia, hypomagnesemia, or clinically unstable cardiac disease, including unstable atrial fibrillation, symptomatic bradycardia, unstable congestive heart failure, or active myocardial ischemia. Periodic electrocardiographic (ECG) monitoring is recommended in these patients. Avoid the use of BELBUCA® in patients with a history of Long QT Syndrome (or an immediate family member with this condition) or those taking Class IA antiarrhythmic medications (e.g., quinidine, procainamide, disopyramide) or Class III antiarrhythmic medications (e.g., sotalol, amiodarone, dofetilide) or other medications that prolong the QT interval.

Severe Hypotension

- BELBUCA® may cause severe hypotension, including orthostatic hypotension and syncope, in ambulatory patients. There is an increased risk in patients whose ability to maintain blood pressure has already been compromised by a reduced blood volume or concurrent administration of certain CNS depressant drugs (e.g., phenothiazines or general anesthetics). Monitor these patients for signs of hypotension after initiating or titrating the dosage of BELBUCA®. In patients with circulatory shock, BELBUCA® may cause vasodilation that can further reduce cardiac output and blood pressure. Avoid the use of BELBUCA® in patients with circulatory shock.

Risks of Use in Patients with Increased Intracranial Pressure, Brain Tumors, Head Injury, or Impaired Consciousness

- In patients who may be susceptible to the intracranial effects of CO_2 retention (e.g., those with evidence of increased intracranial pressure or brain tumors), BELBUCA® may reduce respiratory drive, and the resultant CO_2 retention can further increase intracranial pressure. Monitor such patients for signs of sedation and respiratory depression, particularly when initiating therapy with BELBUCA®.
- Opioids may also obscure the clinical course in a patient with a head injury. Avoid the use of BELBUCA® in patients with impaired consciousness or coma.

IMPORTANT SAFETY INFORMATION about BELBUCA® *cont*

Hepatotoxicity

- Cases of cytolytic hepatitis and hepatitis with jaundice have been observed in individuals receiving sublingual formulations of buprenorphine for the treatment of opioid dependence, both in clinical trials and in post-marketing adverse events reports. For patients at increased risk of hepatotoxicity (e.g., patients with a history of excessive alcohol intake, intravenous drug abuse or liver disease), obtain baseline liver enzyme levels and monitor periodically during treatment with BELBUCA®.

Risk of Overdose in Patients With Moderate or Severe Hepatic Impairment

- In a pharmacokinetic study of subjects dosed with buprenorphine sublingual tablets, buprenorphine plasma levels were found to be higher and the half-life was found to be longer in subjects with moderate and severe hepatic impairment but not in subjects with mild hepatic impairment. For patients with severe hepatic impairment, a dose adjustment is recommended, and patients with moderate or severe hepatic impairment should be monitored for signs and symptoms of toxicity or overdose caused by increased levels of buprenorphine.

Anaphylactic/Allergic Reactions

- Cases of acute and chronic hypersensitivity to buprenorphine have been reported both in clinical trials and in post-marketing experience. The most common signs and symptoms include rashes, hives, and pruritus. Cases of bronchospasm, angioneurotic edema, and anaphylactic shock have been reported.

Risk of Use in Patients with Gastrointestinal Conditions

- BELBUCA® is contraindicated in patients with known or suspected gastrointestinal obstruction, including paralytic ileus.
- BELBUCA® may cause spasm of the sphincter of Oddi. Opioids may cause increases in the serum amylase. Monitor patients with biliary tract disease, including acute pancreatitis, for worsening symptoms.

Increased Risk of Seizures in Patients with Seizure Disorders

- The buprenorphine in BELBUCA® may increase the frequency of seizures in patients with seizure disorders and may increase the risk of seizures occurring in other clinical settings associated with seizures. Monitor patients with a history of seizure disorders for worsened seizure control during BELBUCA® therapy.

Risks of Use in Cancer Patients with Oral Mucositis

- Cancer patients with oral mucositis may absorb buprenorphine more rapidly than intended and are likely to experience transiently higher plasma levels of the opioid. A dose reduction is recommended in these patients. Monitor carefully for signs and symptoms of toxicity or overdose caused by increased levels of buprenorphine.

Risks of Driving and Operating Machinery

- BELBUCA® may impair the mental and physical abilities needed to perform potentially hazardous activities such as driving a car or operating machinery. Warn patients not to drive or operate dangerous machinery unless they are tolerant to side effects of BELBUCA® and know how they will react to the medication.

ADVERSE REACTIONS

- The most common adverse reactions (≥5%) reported by patients treated with BELBUCA® in the clinical trials were nausea, constipation, headache, vomiting, fatigue, dizziness, somnolence, diarrhea, dry mouth, and upper respiratory tract infection.

Please see full Prescribing Information, including Boxed Warning and Medication Guide, for BELBUCA® at belbuca.com.

To report SUSPECTED ADVERSE REACTIONS, contact BioDelivery Sciences International, Inc. at 1-800-469-0261 or the FDA at 1-800-FDA-1088 or www.fda.gov/safety/medwatch.

Intended for healthcare professionals of the United States of America only.

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