MEDICATION GUIDE

Buprenorphine (bue" pre nor' feen) and Naloxone (nal ox' one) Sublingual Tablets, CIII

IMPORTANT: Keep buprenorphine and naloxone sublingual tablets in a secure place away from children. Accidental use by a child is a medical emergency and can result in death. If a child accidentally takes buprenorphine and naloxone sublingual tablets, get emergency help or call 911 right away. Tell your healthcare provider if you are living in a household where there are small children.

What is the most important information I should know about buprenorphine and naloxone sublingual tablets?

- Buprenorphine and naloxone sublingual tablets contains a medicine called buprenorphine. Buprenorphine is an opioid that can cause serious and life-threatening breathing problems, especially if you take or use certain other medicines or drugs.
- Talk to your healthcare provider about naloxone. Naloxone is a medicine that is available to patients for the emergency treatment of an opioid overdose, including accidental use of buprenorphine and naloxone sublingual tablets by a child. If naloxone is given, you must call 911 or get emergency medical help right away to treat an overdose or accidental use of an opioid.
- Buprenorphine and naloxone sublingual tablets may cause serious and life-threatening breathing problems. Get emergency help right away if you:
  - feel faint
  - feel dizzy
  - are confused
  - feel sleepy or uncoordinated
  - have blurred vision
  - have slurred speech
  - are breathing slower than normal
  - cannot think well or clearly
- **Do not take buprenorphine and naloxone sublingual tablets with certain medicines. Taking buprenorphine and naloxone sublingual tablets 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.**
- **Do not inject ("shoot-up") buprenorphine and naloxone sublingual tablets**. Injecting buprenorphine and naloxone sublingual tablets may cause life-threatening infections and other serious health problems, Injecting buprenorphine and naloxone sublingual tablets may cause sudden serious withdrawal symptoms such as pain, cramps, vomiting, diarrhea, anxiety, sleep problems, and cravings.
- **Do not switch from buprenorphine and naloxone sublingual tablets to other medicines that contain buprenorphine** without talking with your healthcare provider. The amount of buprenorphine in a dose of buprenorphine and naloxone sublingual tablets are not the same as in other medicines that contain buprenorphine. Your healthcare provider will prescribe a starting dose of buprenorphine and naloxone sublingual tablets that may be different than other buprenorphine containing medicines you may have been taking.
- Do not stop taking buprenorphine and naloxone sublingual tablets suddenly. You could become sick and have withdrawal symptoms because your body has become used to the medicine (physical dependence). Physical dependence is not the same as drug addiction.
- In an emergency, have family members tell emergency department staff that you are physically dependent on an opioid and are being treated with buprenorphine and naloxone sublingual tablets.
- Never give anyone else your buprenorphine and naloxone sublingual tablets. They could die from taking it. Selling or giving away buprenorphine and naloxone sublingual tablets are against the law.
- Store buprenorphine and naloxone sublingual tablets securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

What are buprenorphine and naloxone sublingual tablets?

- Buprenorphine and naloxone sublingual tablets are a prescription medicine used to treat opioid addiction in adults and is part of a complete treatment program that also includes counseling and behavioral therapy.

Who should not take buprenorphine and naloxone sublingual tablets?

Do not take buprenorphine and naloxone sublingual tablets if you are allergic to buprenorphine or naloxone.

Before taking buprenorphine and naloxone sublingual tablets, tell your healthcare provider about all of your medical conditions, including if you have:

- trouble breathing or lung problems
- an enlarged prostate (men)
- a head injury or brain problem
- a curve in your spine that affects your breathing
- Addison's disease
- problems urinating
- liver, kidney, or gallbladder problems
- alcoholism
- mental health problems
- adrenal gland or thyroid gland problems
- tooth problems, including a history of cavities

Tell your healthcare provider if you are:

- **pregnant or plan to become pregnant.** If you take buprenorphine and naloxone sublingual tablets while pregnant, your baby may have symptoms of opioid withdrawal at birth that could be life-threatening if not recognized and treated. Talk to your healthcare provider if you are pregnant or plan to become pregnant.
- **Breastfeeding or plan to breastfeed**. Buprenorphine and naloxone can pass into your breast milk and harm your baby. Talk to your healthcare provider about the best way to feed your baby if you take buprenorphine and naloxone sublingual tablets. Monitor your baby for increased drowsiness and breathing problems if you breastfeed during treatment with buprenorphine and naloxone sublingual tablets.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, or herbal supplements.

How should I take buprenorphine and naloxone sublingual tablets?

Read the Instructions for Use at the end of this Medication Guide for detailed instructions on how to take buprenorphine and naloxone sublingual tablets

- Take buprenorphine and naloxone sublingual tablets exactly as prescribed by your healthcare provider. Your healthcare provider may change your dose after seeing how it affects you. Do not change your dose unless your healthcare provider tells you to change it.
- Do not take buprenorphine and naloxone sublingual tablets more often than prescribed by your healthcare provider.
- **Buprenorphine and naloxone sublingual tablets are not for occasional or "as needed" use.**
- If you are prescribed a dose of 2 or more buprenorphine and naloxone sublingual tablets at the same time:
  - Ask your healthcare provider for instructions on the right way to take buprenorphine and naloxone sublingual tablets.
- Follow the same instructions every time you take a dose of buprenorphine and naloxone sublingual tablets.
- Take the entire buprenorphine and naloxone sublingual tablet. Do not cut, chew, or swallow buprenorphine and naloxone sublingual tablets, because the medicine will not work as well.
- After buprenorphine and naloxone sublingual tablets are completely dissolved, rinse your mouth with water and swallow. Wait for at least one hour before brushing your 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 buprenorphine and naloxone sublingual tablets.
- If you miss a dose of buprenorphine and naloxone sublingual tablets, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and take the next dose at your regular time. Do not take 2 doses at the same time unless your healthcare provider tells you to. If you are not sure about your dosing, call your healthcare provider.
- Dispose of expired, unwanted, or unused buprenorphine and naloxone sublingual tablets by promptly flushing down the toilet (if a drug take-back option is not readily available). Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.
- **If you take too much buprenorphine and naloxone sublingual tablets or overdose, call Poison Control or get emergency medical help right away.**

What should I avoid while taking buprenorphine and naloxone sublingual tablets?

- **Do not drive, operate heavy machinery, or perform any other dangerous activities until you know how buprenorphine and naloxone sublingual tablets affects you**. Buprenorphine can cause drowsiness and slow reaction times. Buprenorphine and naloxone sublingual tablets can make you sleepy, dizzy, or lightheaded.
- **You should not drink alcohol** or take prescription or over-the-counter medicines that contain alcohol while taking buprenorphine and naloxone sublingual tablets, because this can lead to loss of consciousness or even death.

What are the possible side effects of buprenorphine and naloxone sublingual tablets?

Buprenorphine and naloxone sublingual tablets can cause serious side effects, including:

- **Trouble breathing.** Taking buprenorphine and naloxone sublingual tablets with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants can cause breathing problems that can lead to coma and death.
- **Sleepiness, dizziness, and problems with coordination.**
- **Physical dependence or abuse.**
- **Liver problems.** Call your healthcare provider right away if you notice any of these symptoms:
  - your skin or the white part of your eyes turns yellow (jaundice)
  - dark or "tea-colored" urine
  - light colored stools (bowel movements)
  - loss of appetite
  - pain, aching, or tenderness on the right side of your stomach area
  - nausea
- Your healthcare provider should do blood tests to check your liver before you start taking and while you take buprenorphine and naloxone sublingual tablets.
- **Allergic reaction.** You may have a rash, hives, swelling of your face, wheezing, low blood pressure, or loss of consciousness. Call your healthcare provider or get emergency help right away.
- **Opioid withdrawal.** Call your healthcare provider right away if you get any of these symptoms:
  - shaking
  - sweating more than normal
  - feeling hot or cold more than normal
  - runny nose
  - watery eyes
  - goose bumps
  - diarrhea
  - vomiting
  - muscle aches
- **Decrease in blood pressure.** You may feel dizzy if you get up too fast from sitting or lying down.
- **The most common side effects of buprenorphine and naloxone sublingual tablets include**:
  - headache
  - nausea
  - vomiting
  - constipation
  - pain
  - increased sweating
  - decrease in sleep (insomnia)
- Buprenorphine and naloxone sublingual tablets may affect fertility in males and females. Talk to your healthcare provider if this is a concern for you.
- These are not all the possible side effects of buprenorphine and naloxone sublingual tablets.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of buprenorphine and naloxone sublingual tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not take buprenorphine and naloxone sublingual tablets for a condition for which it was not prescribed. Do not give buprenorphine and naloxone sublingual tablets to other people, even if they have the same symptoms you have. It may harm them and it **is against the law**.

You can ask your doctor or pharmacist for information that is written for healthcare professionals.

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For more information, call Camber Pharmaceuticals, Inc., at 1-866-495-8330.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Rev: 01/2026

INSTRUCTIONS FOR USE

Buprenorphine (bue" pre nor' feen) and Naloxone (nal ox' one) Sublingual Tablets, CIII

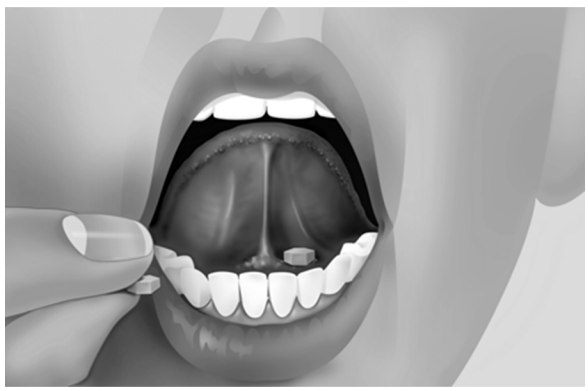
This "Instructions for Use" contains information on how to correctly take buprenorphine and naloxone sublingual tablets.

Important Information You Need to Know Before Taking Buprenorphine and Naloxone sublingual tablets:

- Your healthcare provider should show you how to take buprenorphine and naloxone sublingual tablets the right way.

Preparing to take buprenorphine and naloxone sublingual tablets:

- Put the tablets under your tongue. Let them dissolve completely.



- While buprenorphine and naloxone sublingual tablet is dissolving, do not chew or swallow the tablet because the medicine will not work as well.
- Talking while the tablet is dissolving can affect how well the medicine in buprenorphine and naloxone sublingual tablet is absorbed.
- After buprenorphine and naloxone sublingual tablet is completely dissolved, rinse your mouth with water and swallow. Wait for at least one hour before brushing teeth.
- If you miss a dose of buprenorphine and naloxone sublingual tablet, take your medicine when you remember. If it is almost time for your next dose, skip the missed dose and take the next dose at your regular time. Do not take 2 doses at the same time unless your healthcare provider tells you to. If you are not sure about your dosing, call your healthcare provider.
- Do not stop taking buprenorphine and naloxone sublingual tablets suddenly. You could become sick and have withdrawal symptoms because your body has become used to the medicine. Physical dependence is not the same as drug addiction. Your healthcare provider can tell you more about the differences between physical dependence and drug addiction. To have fewer withdrawal symptoms, ask your healthcare provider how to stop using buprenorphine and naloxone sublingual tablets the right way.

If you take too much buprenorphine and naloxone sublingual tablets or overdose, call Poison Control or get emergency medical help right away.

Storing Buprenorphine and Naloxone Sublingual tablets:

- Store buprenorphine and naloxone sublingual tablets at room temperature between 68° to 77°F (20° to 25°C).
- **Keep buprenorphine and naloxone sublingual tablets in a safe place, out of the sight and reach of children.**

Disposing of Buprenorphine and Naloxone Sublingual tablets:

- Dispose of unused buprenorphine and naloxone sublingual tablets as soon as you no longer need them.
- Dispose of expired, unwanted or unused buprenorphine and naloxone sublingual tablets by promptly flushing down the toilet (if a drug take-back option is not readily available). Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

If you need help with disposal of buprenorphine and naloxone sublingual tablets, please contact Camber Pharmaceuticals, Inc., at 1-866-495-8330.

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