

Dispense the Medication Guide available at: www.paipharma.com/mg/bupre-tab to each patient.

MEDICATION GUIDE

BUPRENORPHINE (bue'' pre nor' feen) SUBLINGUAL TABLETS CIII

Rx Only

IMPORTANT: Keep buprenorphine 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 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 sublingual tablets?

- Buprenorphine sublingual tablets contain 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.
- Ask your healthcare provider about medicines like naloxone or nalmefene that can be used in an emergency to reverse opioid overdose, including accidental use of buprenorphine sublingual tablets by a child. If naloxone or nalmefene is given, you must call 911 or get emergency medical help right away to treat an overdose or accidental use of an opioid.
- Buprenorphine 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 sublingual tablets with certain medicines. Taking buprenorphine sublingual tablets with other opioid medicines, benzodiazepines, gabapentinoids (gabapentin or pregabalin), 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 sublingual tablets.** Injecting buprenorphine sublingual tablets may cause life-threatening infections and other serious health problems.
- **Do not switch from buprenorphine sublingual tablets to other medicines that contain buprenorphine** without talking with your healthcare provider. The amount of buprenorphine in a dose of buprenorphine sublingual tablets is not the same as in other medicines that contain buprenorphine. Your healthcare provider will prescribe a starting dose of buprenorphine sublingual tablets that may be different than other buprenorphine containing medicines you may have been taking.
- Do not stop taking buprenorphine 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 sublingual tablets.
- Never give anyone else your buprenorphine sublingual tablets. They could die from taking it. Selling or giving away buprenorphine sublingual tablets is against the law.
- Store buprenorphine sublingual tablets securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

What is buprenorphine sublingual tablets?

- Buprenorphine sublingual tablets is 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 sublingual tablets?

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

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

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

Tell your healthcare provider if you are:

- **pregnant or plan to become pregnant.** If you take buprenorphine 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 hydrochloride 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 sublingual tablets. Monitor your baby for increased drowsiness and breathing problems if you breastfeed during treatment with buprenorphine 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 sublingual tablets?

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

- After buprenorphine sublingual tablets 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 provider and schedule an appointment with a dentist. Tell your dentist that you have started taking buprenorphine sublingual tablets.
- Take buprenorphine 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 sublingual tablets more often than prescribed by your healthcare provider.
- **Buprenorphine sublingual tablets are not for occasional or "as needed" use.**
- If you are prescribed a dose of 2 or more buprenorphine sublingual tablets at the same time:
 - Ask your healthcare provider for instructions on the right way to take buprenorphine sublingual tablets
- Follow the same instructions every time you take a dose of buprenorphine sublingual tablets
- Take the entire buprenorphine sublingual tablet. Do not cut, chew, or swallow buprenorphine sublingual tablets because the medicine will not work as well.
- If you miss a dose of buprenorphine 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 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 sublingual tablets or overdose, call Poison Control or get emergency medical help right away.**

What should I avoid while taking buprenorphine sublingual tablets?

- **Do not drive, operate heavy machinery, or perform any other dangerous activities until you know how buprenorphine sublingual tablets affect you.** Buprenorphine can cause drowsiness and slow reaction times. Buprenorphine 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 sublingual tablets, because this can lead to loss of consciousness or even death.

What are the possible side effects of buprenorphine sublingual tablets?

Buprenorphine sublingual tablets can cause serious side effects including:

- **Trouble breathing.** Taking buprenorphine sublingual tablets with other opioid medicines, benzodiazepines, gabapentinoids (gabapentin or pregabalin), alcohol or other central nervous system depressants (including street drugs) 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 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 sublingual tablets include:**
 - headache
 - nausea
 - vomiting
 - constipation
 - pain
 - increased sweating
 - decrease in sleep (insomnia)
- Buprenorphine 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 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 sublingual tablets

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

What are the ingredients in Buprenorphine Sublingual Tablets?

Active ingredient: buprenorphine hydrochloride, USP

Inactive ingredients: Lactose monohydrate, Mannitol, Corn starch, Citric acid anhydrous, Sodium citrate, Povidone K30, Sodium stearyl Fumarate, Purified water.

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

For more information, call 1-800-845-8210.

Manufactured by:
Ethypharm S.A.
76121 Le Grand Quevilly Cedex
France

Distributed by:
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INSTRUCTIONS FOR USE
BUPRENORPHINE (bue'' pre nor' feen) SUBLINGUAL TABLETS CIII

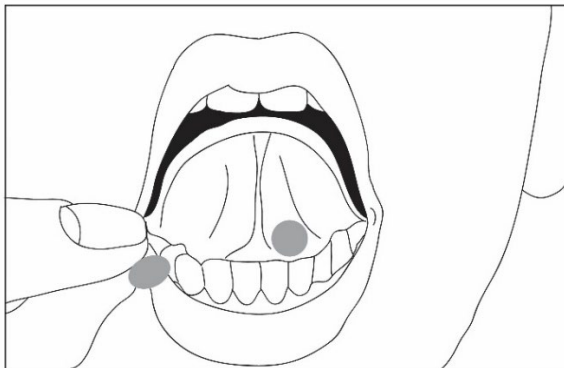
This “Instructions for Use” contains information on how to correctly take buprenorphine sublingual tablets.

Important Information You Need to Know Before Taking buprenorphine sublingual tablets:

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

Preparing to take buprenorphine sublingual tablets:

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



- While buprenorphine 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 sublingual tablet is absorbed.
- After buprenorphine sublingual tablets 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 sublingual tablets, 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 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 sublingual tablets the right way.

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

Storing buprenorphine sublingual tablets:

- Store buprenorphine sublingual tablets at room temperature between 59°F and 86°F (15°C to 30°C).
- **Keep buprenorphine sublingual tablets in a safe place, out of the sight and reach of children.**

Disposing of buprenorphine sublingual tablets:

- Dispose of unused buprenorphine sublingual tablets as soon as you no longer need them.
- Dispose of expired, unwanted or unused buprenorphine 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 sublingual tablets, call 1-800-845-8210.

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