

Dispense with Medication Guide available at: https://www.sunpharma.com/usa/products

MEDICATION GUIDE Buprenorphine Sublingual Tablets, () (BUE-pre-NOR-feen)

IMPORTANT:

Keep buprenorphine sublingual tablet 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 tablet, 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 tablet?

- Buprenorphine sublingual tablet 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 sublingual tablet 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 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 tablet with certain medicines. Taking buprenorphine sublingual tablet 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 sublingual tablet. Injecting buprenorphine sublingual tablet may cause life-threatening infections and other serious health problems.
- Do not switch from buprenorphine sublingual tablet to other medicines that contain buprenorphine without talking with your healthcare provider. The amount of buprenorphine in a dose of buprenorphine sublingual tablet is not the same as in other medicines that contain buprenorphine. Your healthcare provider will prescribe a starting dose of buprenorphine sublingual tablet 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 tablet.

- Never give anyone else your buprenorphine sublingual tablet. They could die from taking it. Selling or giving away buprenorphine sublingual tablets is against the law.
- Store buprenorphine sublingual tablet 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 tablet?

• Buprenorphine sublingual tablet 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 tablet? Do not take buprenorphine sublingual tablet 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:

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

- After buprenorphine sublingual tablet 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.

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

- Take buprenorphine sublingual tablet 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 tablet more often than prescribed by your healthcare provider.

- Buprenorphine sublingual tablets is 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 tablet.
- Follow the same instructions every time you take a dose of buprenorphine sublingual tablet.
- Take the entire buprenorphine sublingual tablet. Do not cut, chew, or swallow buprenorphine sublingual tablet because the medicine will not work as well.
- If you miss a dose of buprenorphine sublingual tablet, 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 many buprenorphine sublingual tablets or overdose, call Poison Control or get emergency medical help right away.

What should I avoid while taking buprenorphine	• Allergic reaction. You may have a rash,	sublingual tablet to other people, even if they	 If you miss a dose of buprenorphine sublingual tablet, take your medicine when you remember. If 	
sublingual tablet?	hives, swelling of your face, wheezing,	have the same symptoms you have. It may	it is almost time for your next dose, skip the	
 Do not drive, operate heavy machinery, 	low blood pressure, or loss of	harm them and it is against the law .	missed dose and take the next dose at your	
or perform any other dangerous activities	consciousness. Call your healthcare	You can ask your doctor or pharmacist for	regular time. Do not take 2 doses at the same	
until you know how buprenorphine	provider or get emergency help right away.	information that is written for healthcare professionals.	time unless your healthcare provider tells you to.	-
affects you. Buprenorphine can cause	Opioid withdrawal. Call your healthcare	For more information call 1-800-818-4555.	If you are not sure about your dosing, call your	This "Instructions for Use" has been approved by
drowsiness and slow reaction times.	provider right away if you get any of these		healthcare provider.	the U.S. Food and Drug Administration.
Buprenorphine can make you sleepy, dizzy,	symptoms:	This Medication Guide has been approved by	• Do not stop taking buprenorphine sublingual	
or lightheaded.	 shaking 	the U.S. Food and Drug Administration.	tablet suddenly. You could become sick and have	Distributed by:
• You should not drink alcohol or take	 sweating more than normal 	5	withdrawal symptoms because your body has	Sun Pharmaceutical Industries, Inc.
prescription or over-the-counter	 feeling hot or cold more than normal 		become used to the medicine. Physical	Cranbury, NJ 08512
medicines that contain alcohol while	 runny nose 	INSTRUCTIONS FOR USE	dependence is not the same as drug addiction.	Manufactured but
taking buprenorphine sublingual tablet,	 watery eyes 	Buprenorphine Sublingual Tablets, 🖲	Your healthcare provider can tell you more about	Sun Pharmaceutical Industries Ltd.
because this can lead to loss of	 goose bumps 	(BUE-pre-NOR-feen)	the differences between physical dependence and drug addiction. To have fewer withdrawal	
consciousness or even death.	 diarrhea 	This "Instructions for Use" contains information	symptoms, ask your healthcare provider how to	SUTVEY NO. 259/15, Dadra-396 191, U.T. of D & NH), India.
	 vomiting 	This "Instructions for Use" contains information on how to correctly take buprenorphine	stop using buprenorphine sublingual tablet the	
What are the possible side effects of	 muscle aches 	sublingual tablets.	right way.	
buprenorphine sublingual tablets?	Decrease in blood pressure. You may	Subiligual lablets.		
Buprenorphine sublingual tablets can cause	feel dizzy if you get up too fast from sitting	Important Information You Need to Know Before	If you take too many buprenorphine sublingual	
serious side effects, including:	or lying down. • The most common side effects of	Taking Buprenorphine sublingual tablets:	tablets or overdose, call Poison Control or get	
• Trouble breathing. Taking buprenorphine	 The most common side energy of buprenorphine sublingual tablets include: 	Your healthcare provider should show you how to	emergency medical help right away.	
sublingual tablets with other opioid	 headache 	take buprenorphine sublingual tablets the right		
medicines, benzodiazepines, alcohol, or	 nausea 	way.	Storing Buprenorphine Sublingual tablets	
other central nervous system depressants	• vomiting		• Store buprenorphine sublingual tablets at room	
can cause breathing problems that can	 constipation 	Preparing to take buprenorphine sublingual	temperature between 20° to 25°C (68° to 77°F). Protect from light.	
lead to coma and death.	• pain	tablets:	• Keep buprenorphine sublingual tablets in a	
• Sleepiness, dizziness, and problems	 increased sweating 	Put the tablets under your tongue. Let them	safe place, out of the sight and reach of	
with coordination.	decrease in sleep (insomnia)	dissolve completely.	children.	
 Physical dependence or abuse. 	Buprenorphine sublingual tablet may affect		Retain blister card in carton until time of use.	
• Liver problems. Call your healthcare	fertility in males and females. Talk to your			
provider right away if you notice any of	healthcare provider if this is a concern for		Disposing of Buprenorphine Sublingual tablets:	
these symptoms:	you. These are not all the possible side effects of		 Dispose of unused buprenorphine sublingual 	
 your skin or the white part of your eyes 	buprenorphine sublingual tablets.		tablets as soon as you no longer need them.	
turns yellow (jaundice)	Call your doctor for medical advice about side		 Dispose of expired, unwanted or unused 	
 loss of appetite 	effects. You may report side effects to FDA at		buprenorphine sublingual tablets by promptly flushing down the toilet (if a drug take-back	
 dark or "tea-colored" urine 	1-800-FDA-1088.		option is not readily available). Visit	
 pain, aching, or tenderness on the right 			www.fda.gov/drugdisposal for additional	
side of your stomach area	General information about the safe and		information on disposal of unused medicines.	
 light colored stools (bowel movements) 	effective use of buprenorphine sublingual	• While buprenorphine sublingual tablet is		
 ngu colored stools (bowermovements) nausea 	tablet.	dissolving, do not chew or swallow the tablet		
 Your healthcare provider should do blood 	Medicines are sometimes prescribed for purposes other than those listed in a	because the medicine will not work as well.		
tests to check your liver before you start	Medication Guide. Do not take buprenorphine	• Talking while the tablet is dissolving can affect		
taking and while you take buprenorphine	sublingual tablet for a condition for which it	how well the medicine in buprenorphine		
sublingual tablets.	was not prescribed. Do not give buprenorphine	sublingual tablet is absorbed.		
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