

Medication Guide

BUPREXIL (bu-preks-il) (buprenorphine and naloxone) sublingual film for sublingual use, CIII

IMPORTANT: Accidental use of BUPREXIL by a child is a medical emergency and can result in death. If a child accidentally takes BUPREXIL, get emergency help right away. Keep BUPREXIL in a secure place away from children.

What is the most important information I should know about BUPREXIL?

- **BUPREXIL may cause serious and life-threatening breathing problems. Get emergency help right away if you:**
 - o feel faint
 - o feel dizzy
 - o are confused
 - o feel sleepy or uncoordinated
 - o have blurred vision
 - o have slurred speech
 - o are breathing slower than normal
 - o cannot think well or clearly
- **Severe drowsiness, decreased awareness, breathing problems, coma, overdose or death** can happen if you take BUPREXIL with other opioid medicines, benzodiazepines, sleeping pills, sedatives, tranquilizers, antihistamines, or antidepressants. Get emergency help right away if you have any of these symptoms.
- **Talk to your healthcare provider about naloxone**, a medicine for the emergency treatment of an opioid overdose or accidental use of an opioid. BUPREXIL contains an opioid medicine called buprenorphine. It is safe to give naloxone to people of all ages, including children. If naloxone is given, get emergency medical help right away.
- **Do not inject (“shoot-up”) BUPREXIL.** Injecting BUPREXIL may cause life-threatening infections and other serious health problems. Injecting BUPREXIL may cause sudden serious withdrawal symptoms such as pain, cramps, vomiting, diarrhea, anxiety, sleep problems, and cravings.
- **Do not switch from BUPREXIL to other medicines that contain buprenorphine** without talking to your healthcare provider. The amount of buprenorphine in a dose of BUPREXIL may not be the same as in other medicines that contain buprenorphine. Your healthcare provider will prescribe a starting dose of BUPREXIL that may be different than other buprenorphine containing medicines you may have been taking.
- Even if you take your dose correctly as prescribed, you are at risk for abuse and misuse that can lead to overdose and death.
- BUPREXIL is not for occasional or “as needed” use. Do not stop taking BUPREXIL 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 the emergency department staff that you are physically dependent on an opioid and are being treated with BUPREXIL.
- Never give anyone else your BUPREXIL. They could die from taking it. Selling or giving away BUPREXIL is against the law.
- Store BUPREXIL securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

What is BUPREXIL?

- BUPREXIL 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 BUPREXIL?

- **Do not take BUPREXIL if you are allergic to buprenorphine or naloxone.**

Before taking BUPREXIL, 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
- 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 BUPREXIL 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.** BUPREXIL 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 BUPREXIL. Monitor your baby for increased drowsiness and breathing problems if you breastfeed during treatment with BUPREXIL.

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

How should I take BUPREXIL?

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

- Take BUPREXIL 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 BUPREXIL more often than prescribed by your healthcare provider.
- Use the entire BUPREXIL sublingual film. Do not cut, tear, chew, or swallow the sublingual film.
- If you miss a dose of BUPREXIL, 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 BUPREXIL by removing the BUPREXIL sublingual film from the foil packaging, and 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 BUPREXIL or overdose, get emergency medical help right away.**

What should I avoid while taking BUPREXIL?

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

What are possible side effects of BUPREXIL?

BUPREXIL can cause serious side effects including:

- **Trouble breathing.** Taking BUPREXIL with 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:
 - o your skin or the white part of your eyes turns yellow (jaundice)
 - o dark or “tea-colored” urine
 - o light colored stools (bowel movements)
 - o loss of appetite
 - o pain, aching, or tenderness on the right side of your stomach area
 - o nausea

Your healthcare provider should do blood tests to check the liver before you start taking and while you take BUPREXIL.

- **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:
 - o shaking
 - o sweating more than normal
 - o feeling hot or cold more than normal
 - o runny nose
 - o watery eyes
 - o goose bumps
 - o diarrhea
 - o vomiting
 - o muscle aches
 - o
- **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 BUPREXIL include:

- headache
- nausea
- vomiting
- constipation
- pain
- increased sweating
- decrease in sleep (insomnia)

BUPREXIL sublingual film 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 BUPREXIL.

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 BUPREXIL.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use BUPREXIL for a condition for which it was not prescribed. Do not give BUPREXIL 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 pharmacist or healthcare provider or for information that is written for health professionals.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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