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 uses buprenorphine and naloxone sublingual tablets, get emergency help right away.

Read this Medication Guide before you start taking buprenorphine and naloxone sublingual tablets and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor. Talk to your doctor or pharmacist if you have questions about buprenorphine and naloxone sublingual tablets.

Share the important information in this Medication Guide with members of your household.

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

- Buprenorphine and naloxone sublingual tablets can cause serious and life-threatening breathing problems. Call your doctor right away or get emergency help if:
    - You feel faint, dizzy or confused
    - Your breathing gets much slower than is normal for you

These can be signs of an overdose or other serious problems.

- Buprenorphine and naloxone sublingual tablets contain an opioid that can cause physical dependence.
    - Do not stop taking buprenorphine and naloxone sublingual tablets without talking to your doctor. You could become sick with uncomfortable withdrawal signs and symptoms because your body has become used to this medicine
    - Physical dependence is not the same as drug addiction
    - Buprenorphine and naloxone sublingual tablets are not for occasional or “as needed” use
- An overdose, and even death, can happen if you take benzodiazepines, sedatives, tranquilizers, or alcohol while using buprenorphine and naloxone sublingual tablets. Ask your doctor what you should do if you are taking one of these.
- Call a doctor or get emergency help right away if you:
    - Feel sleepy and uncoordinated
    - Have blurred vision
    - Have slurred speech

    - Cannot think well or clearly
    - Have slowed reflexes and breathing
- Do not inject ("shoot-up") buprenorphine and naloxone sublingual tablets.
    - Injecting this medicine may cause life-threatening infections and other serious health problems.
    - Injecting buprenorphine and naloxone sublingual tablets may cause serious withdrawal symptoms such as pain, cramps, vomiting, diarrhea, anxiety, sleep problems and cravings.
- In an emergency, have family members tell the emergency department staff that you are physically dependent on an opioid and are being treated with buprenorphine and naloxone sublingual tablets.

What are buprenorphine and naloxone sublingual tablets?

- Buprenorphine and naloxone sublingual tablets are a prescription medicine used to treat adults who are addicted to (dependent on) opioid drugs (either prescription or illegal), as part of a complete treatment program that also includes counseling and behavioral therapy.

Buprenorphine and naloxone sublingual tablets are a controlled substance (CIII) because they contain buprenorphine, which can be a target for people who abuse prescription medicines or street drugs. Keep your buprenorphine and naloxone sublingual tablets in a safe place to protect it from theft. Never give your buprenorphine and naloxone sublingual tablets to anyone else; it can cause death or harm them. Selling or giving away this medicine is against the law.

- It is not known if buprenorphine and naloxone sublingual tablets are safe or effective in children.

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.

What should I tell my doctor before taking buprenorphine and naloxone sublingual tablets?

Buprenorphine and naloxone sublingual tablets may not be right for you. Before taking buprenorphine and naloxone sublingual tablets, tell your doctor if you:

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

- Have mental problems such as hallucinations (seeing or hearing things that are not there)
- Have any other medical condition
- Are pregnant or plan to become pregnant. It is not known if buprenorphine and naloxone sublingual tablets will harm your unborn baby. If you take buprenorphine and naloxone sublingual tablets while pregnant, your baby may have symptoms of withdrawal at birth. Talk to your doctor if you are pregnant or plan to become pregnant.
- Are breast feeding or plan to breast feed. Buprenorphine and naloxone can pass into your milk and may harm the baby. Talk to your doctor about the best way to feed your baby if you take buprenorphine and naloxone sublingual tablets. Breast feeding is not recommended while taking buprenorphine and naloxone sublingual tablets.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins and herbal supplements. Buprenorphine and naloxone sublingual tablets may affect the way other medicines work and other medicines may affect how buprenorphine and naloxone sublingual tablets work. Some medicines may cause serious or life-threatening medical problems when taken with buprenorphine and naloxone sublingual tablets.

Sometimes the doses of certain medicines and buprenorphine and naloxone sublingual tablets may need to be changed if used together. Do not take any medicine while using buprenorphine and naloxone sublingual tablets until you have talked with your doctor. Your doctor will tell you if it is safe to take other medicines while you are using buprenorphine and naloxone sublingual tablets.

Be especially careful about taking other medicines that may make you sleepy, such as pain medicines, tranquilizers, antidepressant medicines, sleeping pills, anxiety medicines or antihistamines.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist each time you get a new medicine.

How should I take buprenorphine and naloxone sublingual tablets?

- Always take buprenorphine and naloxone sublingual tablets exactly as your doctor tells you. Your doctor may change your dose after seeing how it affects you. Do not change your dose unless your doctor tells you to change it.
- Do not take buprenorphine and naloxone sublingual tablets more often than prescribed by your doctor.
- If you are prescribed a dose of 2 or more buprenorphine and naloxone sublingual tablets at the same time:
    - Ask your doctor 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
- Put the tablets under your tongue. Let them dissolve completely.

- While buprenorphine and naloxone sublingual tablets are 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 tablets is absorbed.
- If you miss a dose of buprenorphine and naloxone 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 doctor tells you to. If you are not sure about your dosing, call your doctor.
- 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 doctor can tell you more about the differences between physical dependence and drug addiction. To have fewer withdrawal symptoms, ask your doctor 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.**

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 this medication affects you.** Buprenorphine can cause drowsiness and slow reaction times. This may happen more often in the first few weeks of treatment when your dose is being changed, but can also happen if you drink alcohol or take other sedative drugs when you take buprenorphine and naloxone sublingual tablets.
- **You should not drink alcohol** while using buprenorphine and naloxone sublingual tablets, as 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:

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

- **Respiratory problems.** You have a higher risk of death and coma if you take buprenorphine and naloxone sublingual tablets with other medicines, such as benzodiazepines.
- **Sleepiness, dizziness, and problems with coordination**
- **Dependency or abuse**
- **Liver problems.** Call your doctor right away if you notice any of these signs of liver problems: Your skin or the white part of your eyes turning yellow (jaundice), urine turning dark, stools turning light in color, you have less of an appetite, or you have stomach (abdominal) pain or nausea. Your doctor should do tests 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, or loss of blood pressure and consciousness. Call a doctor or get emergency help right away.
- **Opioid withdrawal.** This can include: shaking, sweating more than normal, feeling hot or cold more than normal, runny nose, watery eyes, goose bumps, diarrhea, vomiting and muscle aches. Tell your doctor if you develop any of these symptoms.
- **Decrease in blood pressure.** You may feel dizzy if you get up too fast from sitting or lying down.

Common side effects of buprenorphine and naloxone sublingual tablets include:

- Headache
- Nausea
- Vomiting
- Increased sweating
- Drug withdrawal syndrome
- Constipation
- Decrease in sleep (insomnia)
- Pain
- Swelling of the extremities

Tell your doctor about any side effect that bothers you or that does not go away.

These are not all the possible side effects of buprenorphine and naloxone sublingual tablets. For more information, ask your doctor or pharmacist.

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

How should I store buprenorphine and naloxone sublingual tablets?

- Store buprenorphine and naloxone sublingual tablets at 68°F to 77°F (20°C to 25°C). [See USP Controlled Room Temperature.]
- **Keep buprenorphine and naloxone sublingual tablets in a safe place, out of the sight and reach of children.**

How should I dispose of unused buprenorphine and naloxone sublingual tablets?

- Dispose of unused buprenorphine and naloxone sublingual tablets as soon as you no longer need them.
- Flush unused tablets down the toilet.

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 use 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.

This Medication Guide summarizes the most important information about buprenorphine and naloxone sublingual tablets. If you would like more information, talk to your doctor or pharmacist. You can ask your doctor or pharmacist for information that is written for healthcare professionals.

For more information call 1-800-962-8364.

What are the ingredients in buprenorphine and naloxone sublingual tablets?

Active Ingredients: buprenorphine and naloxone

Inactive Ingredients: anhydrous citric acid, corn starch, FD & C yellow no. 6, lactose monohydrate, lemon-lime flavor, magnesium stearate, mannitol, povidone, sodium citrate dihydrate, and sucralose.

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

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