PATIENT & CAREGIVER EDUCATION

Buprenorphine and Naloxone

This information from Lexicomp® explains what you need to know about this medication, including what it’s used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US
Bunavail [DSC]; Suboxone; Zubsolv

Brand Names: Canada
PMS-Buprenorphine-Naloxone; Suboxone; TEVA-Buprenorphine/Naloxone

What is this drug used for?

- It is used to treat opioid addiction. Opioid drugs include heroin and prescription pain drugs like oxycodone and morphine.
- Do not use for pain relief or on an as needed basis.

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you have liver disease.
- If you have not been taking an opioid drug.
- If you have taken certain drugs for depression or Parkinson’s disease in the last 14 days. This includes isocarboxazid, phenelzine, tranylcypromine, selegiline, or rasagiline. Very high blood pressure may happen.
If you are taking any of these drugs: Linezolid or methylene blue.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

**What are some things I need to know or do while I take this drug?**

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Avoid driving and doing other tasks or actions that call for you to be alert until you see how this drug affects you.
- To lower the chance of feeling dizzy or passing out, rise slowly if you have been sitting or lying down. Be careful going up and down stairs.
- Your doctor may order naloxone to keep with you to help treat an opioid overdose if needed. Opioid overdose may happen if you start taking opioid drugs again or if too much of this drug is taken. If you have questions about how to get or use naloxone, talk with your doctor or pharmacist. If you think there has been an opioid overdose, get medical care right away even if naloxone has been used.
- Long-term use of an opioid drug may lead to lower sex hormone levels. Call your doctor if you have a lowered interest in sex, fertility problems, no menstrual period, or ejaculation problems.
- Even one dose of this drug may be deadly if it is taken by someone else or by accident, especially in children. If this drug is taken by someone else or by accident, get medical help right away.
- Signs of opioid withdrawal have happened with this drug. Call your doctor right away if you have sweating, chills, diarrhea or stomach pain that is not normal, anxiety, feeling irritable, or yawning.
Liver problems have rarely happened with this drug. Sometimes, this has been deadly. Call your doctor right away if you have signs of liver problems like dark urine, tiredness, decreased appetite, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.

This drug has an opioid in it. Severe side effects have happened when opioid drugs were used with benzodiazepines, alcohol, marijuana, other forms of cannabis, or street drugs. This includes severe drowsiness, breathing problems, and death. Benzodiazepines include drugs like alprazolam, diazepam, and lorazepam. If you have questions, talk with the doctor.

Do not take with alcohol or products that have alcohol. Unsafe and sometimes deadly effects may happen.

Dental problems like cavities, infections, and loss of teeth have happened with buprenorphine products that are dissolved in the mouth. This has even happened in people who did not already have dental problems. Call your doctor and your dentist right away if you have any problems with your teeth or gums.

If you are pregnant or plan to get pregnant, talk with your doctor right away. Using this drug for a long time during pregnancy may lead to withdrawal in the newborn baby. Withdrawal in the newborn can be life-threatening if not treated.

Tell your doctor if you are breast-feeding or plan to breast-feed. This drug passes into breast milk and may harm your baby.

**What are some side effects that I need to call my doctor about right away?**

**WARNING/CAUTION:** Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in
the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.

- Signs of low blood sugar like dizziness, headache, feeling sleepy, feeling weak, shaking, a fast heartbeat, confusion, hunger, or sweating.
- Change in eyesight.
- Feeling nervous and excitable.
- Change in balance.
- Depression or other mood changes.
- Feeling confused, not able to focus, or change in behavior.
- Extra muscle action or slow movement.
- Slurred speech.
- Feeling sluggish, drunk, or out of sorts.
- A heartbeat that does not feel normal.
- Noisy breathing.
- Breathing problems during sleep (sleep apnea).
- This drug may cause very bad and sometimes deadly breathing problems. Call your doctor right away if you have slow, shallow, or trouble breathing.
- Get medical help right away if you feel very sleepy, very dizzy, or if you pass out. Caregivers or others need to get medical help right away if the patient does not respond, does not answer or react like normal, or will not wake up.
- Taking an opioid drug like this drug may lead to a rare but severe adrenal gland problem. Call your doctor right away if you feel very tired or weak, you pass out, or you have severe dizziness, very upset stomach, throwing up, or decreased appetite.
- A severe and sometimes deadly problem called serotonin syndrome may happen if you take this drug with certain other drugs. Call your doctor right away if you have agitation; change in balance; confusion;
hallucinations; fever; fast or abnormal heartbeat; flushing; muscle twitching or stiffness; seizures; shivering or shaking; sweating a lot; severe diarrhea, upset stomach, or throwing up; or severe headache.

**What are some other side effects of this drug?**

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

**All products:**

- Feeling dizzy, sleepy, tired, or weak.
- Constipation, diarrhea, stomach pain, upset stomach, or throwing up.
- Headache.
- Trouble sleeping.
- Sweating a lot.
- Flushing.
- Back pain.

**Under the tongue (sublingual) film:**

- Burning.
- Numbness or tingling in the mouth.
- Pain where it was placed.
- Redness.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

You may report side effects to the FDA at 1-800-332-1088. You may also report side effects at [https://www.fda.gov/medwatch](https://www.fda.gov/medwatch).
How is this drug best taken?
Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

All products:

- Take this drug at the same time of day.
- Do not chew, cut, or swallow this drug.
- Do not eat, drink, smoke, or talk while this drug is dissolving.
- Take by mouth only. Very bad and sometimes deadly side effects may happen if this drug is injected.
- After this drug has dissolved, take a large sip of water, swish it around in your mouth, and swallow. Wait at least 1 hour before brushing your teeth.
- Take good care of your teeth. See a dentist often.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- If you are 65 or older, use this drug with care. You could have more side effects.
- This drug may be habit-forming with long-term use.
- This drug has a risk of abuse and misuse. Use this drug only as you were told by your doctor. Tell your doctor if you have ever abused or been addicted to any drugs or alcohol.
- You will be watched closely to make sure you do not misuse, abuse, or become addicted to this drug.
- Do not stop taking this drug all of a sudden without calling your doctor. You may have a greater risk of signs of withdrawal. If you need to stop this drug, you will want to slowly stop it as ordered by your doctor.
- Many drugs interact with this drug and can raise the chance of side effects like deadly breathing problems. Talk with your doctor and pharmacist to make sure it is safe to use this drug with all of your drugs.
All film products:

- Open right before use.
- Be sure your hands are dry before you touch this drug.
- This drug must be taken whole. Do not cut or tear this drug. Do not touch the film with your tongue or finger once it has been placed.

Under the tongue (sublingual) film:

- Some products need to be placed under the tongue. Some products may be placed under the tongue or on the inside of the cheek. Be sure you know how this drug needs to be taken. If you are not sure, check with the pharmacist.
- If using under the tongue, wet mouth with water. Place film under the tongue close to the base on the left or right side and let it dissolve.
- If using on the inside of the cheek, wet the inside of your cheek with your tongue or water. Place the film inside the mouth on a wet cheek and let it dissolve.
- If using 2 films, place on opposite sides. Try not to let films touch.
- If using 3 films, place the third film under the tongue after the first 2 films have dissolved.

Cheek film:

- Wet the inside of your cheek with your tongue or water.
- Place the film inside the mouth on a wet cheek. Hold for 5 seconds so it sticks to the cheek. Let it dissolve.
- Place the side of the film with the writing against the inside of the cheek.
- If using 2 films, place on opposite sides. If using many films, do not place more than 2 films on the inside of 1 cheek at a time.
Under the tongue (sublingual) tablet:

- Place tablet under the tongue and let dissolve.
- If your doctor tells you to use more than 1 tablet at a time, ask your doctor how to take them.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.
- If you are not sure what to do if you miss a dose, call your doctor.

How do I store and/or throw out this drug?

All products:

- Store at room temperature in a dry place. Do not store in a bathroom.
- Store this drug in a safe place where children cannot see or reach it, and where other people cannot get to it. A locked box or area may help keep this drug safe. Keep all drugs away from pets.

All film products:

- Do not freeze.
- Store in foil pouch until ready for use.

General drug facts

- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.
- If your symptoms or health problems do not get better or if they become worse, call your doctor.
Do not share your drugs with others and do not take anyone else’s drugs.

Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.

This drug comes with an extra patient fact sheet called a Medication Guide. Read it with care. Read it again each time this drug is refilled. If you have any questions about this drug, please talk with the doctor, pharmacist, or other health care provider.

If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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