

**MEDICATION GUIDE**  
**SUBUTEX<sup>®</sup> (Sub-u-tex)**  
**(buprenorphine)**  
**Sublingual Tablet (CIII)**

**IMPORTANT:**

Keep SUBUTEX 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 SUBUTEX, get emergency help right away.

Read this Medication Guide that comes with SUBUTEX before you start taking it 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 SUBUTEX.

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

**What is the most important information I should know about SUBUTEX?**

- SUBUTEX 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 youThese can be signs of an overdose or other serious problems.
- Do not switch from SUBUTEX to other medicines that contain buprenorphine without talking with your doctor. The amount of buprenorphine in a dose of SUBUTEX may not be the same as the amount of buprenorphine in other medicines that contain buprenorphine. Your doctor will prescribe a starting dose of SUBUTEX that may be different than other buprenorphine containing medicines you may have been taking.
- SUBUTEX contains an opioid that can cause physical dependence.
  - Do not stop taking SUBUTEX 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
  - SUBUTEX is not for occasional or “as needed” use
- An overdose, and even death, can happen if you take benzodiazepines, sedatives, tranquilizers, antidepressants, or alcohol while using SUBUTEX. 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”) SUBUTEX.
  - Injecting SUBUTEX may cause life-threatening infections and other serious health problems.
  - Injecting SUBUTEX 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 SUBUTEX.

### **What is SUBUTEX?**

- SUBUTEX is a prescription medicine used to begin treatment in adults who are addicted to (dependent on) opioid drugs (either prescription or illegal drugs), as part of a complete treatment program that also includes counseling and behavioral therapy.
- SUBUTEX is most often used for the first 1 or 2 days to help you start with treatment.

SUBUTEX is a controlled substance (CIII) because it contains buprenorphine, which can be a target for people who abuse prescription medicines or street drugs. Keep your SUBUTEX in a safe place to protect it from theft. Never give your SUBUTEX 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 SUBUTEX is safe or effective in children.

### **Who should not take SUBUTEX?**

Do not take SUBUTEX if you are allergic to buprenorphine.

### **What should I tell my doctor before taking SUBUTEX?**

**SUBUTEX may not be right for you. Before taking SUBUTEX, tell your doctor if you:**

- Have liver or kidney problems
- 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 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. If you take SUBUTEX while pregnant, your baby may have symptoms of opioid withdrawal or respiratory depression at birth. Talk to your doctor if you are pregnant or plan to become pregnant.
- Are breastfeeding or plan to breastfeed. SUBUTEX can pass into your milk and may harm your baby. Talk to your doctor about the best way to feed your baby if you take SUBUTEX. Monitor your baby for increased sleepiness and breathing problems.

**Tell your doctor about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. SUBUTEX may affect the way other medicines work, and other medicines may affect how SUBUTEX works. Some medicines may cause serious or life-threatening medical problems when taken with SUBUTEX.

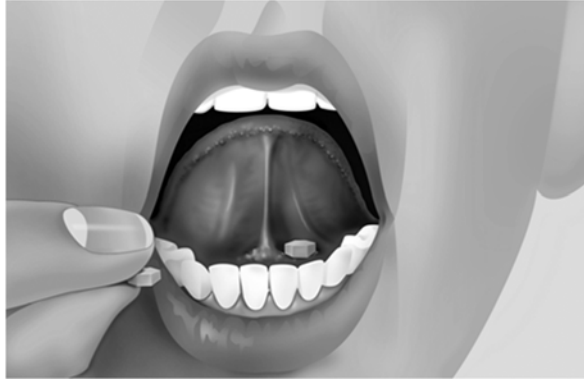
Sometimes the doses of certain medicines and SUBUTEX may need to be changed if used together. Do not take any medicine while using SUBUTEX until you have talked with your doctor. Your doctor will tell you if it is safe to take other medicines while you are taking SUBUTEX.

**Be especially careful about taking other medicines that may make you sleepy**, such as pain medicines, tranquilizers, 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 SUBUTEX?**

- Always take SUBUTEX 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 SUBUTEX more often than prescribed by your doctor.
- If you are prescribed a dose of 2 or more SUBUTEX tablets at the same time:
  - Ask your doctor for instructions on the right way to take SUBUTEX tablets
  - Follow the same instructions every time you take a dose of SUBUTEX tablet
- Put the tablets under your tongue. Let them dissolve completely.



- While SUBUTEX 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 SUBUTEX is absorbed.
- If you miss a dose of SUBUTEX, 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 SUBUTEX 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 SUBUTEX the right way.
- **If you take too much SUBUTEX or overdose, call Poison Control or get emergency medical help right away.**

#### **What should I avoid while taking SUBUTEX?**

- **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 SUBUTEX.
- **You should not drink alcohol** while using SUBUTEX, as this can lead to loss of consciousness or death.

#### **What are the possible side effects of SUBUTEX?**

##### **SUBUTEX can cause serious side effects including:**

- See **“What is the most important information I should know about SUBUTEX?”**
- **Respiratory problems.** You have a higher risk of death and coma if you take SUBUTEX 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 SUBUTEX.
- **Allergic reaction.** You may have a rash, hives, swelling of the 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 SUBUTEX include:**

- Nausea
- Vomiting
- Drug withdrawal syndrome
- Headache
- Sweating
- Numb mouth
- Constipation
- Swollen and/or painful tongue
- The inside of your mouth is more red than normal
- Intoxication (feeling lightheaded or drunk)
- Disturbance in attention
- Irregular heart beat (palpitations)
- Decrease in sleep (insomnia)
- Blurred vision
- Back pain
- Fainting
- Dizziness
- Sleepiness

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 SUBUTEX. 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 SUBUTEX?**

- Store SUBUTEX at room temperature between 68°F and 77°F (20°C to 25°C).
- **Keep SUBUTEX in a safe place, out of the sight and reach of children.**

### **How should I dispose of unused SUBUTEX?**

- Dispose of unused SUBUTEX as soon as you no longer need them.
  - Unused tablets should be flushed down the toilet.
- If you need help with disposal of SUBOXONE, call 1-877-782-6966.

### **General information about the safe and effective use of SUBUTEX**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not take SUBUTEX for a condition for which it was not prescribed. Do not give SUBUTEX 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 SUBUTEX. 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 1-877-782-6966.

### **What are the ingredients in SUBUTEX sublingual tablets?**

**Active Ingredient:** buprenorphine

**Inactive Ingredients:** lactose, mannitol, cornstarch, povidone K30, citric acid, sodium citrate, and magnesium stearate

Manufactured for Indivior Inc.

North Chesterfield, VA 23235

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

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