

**SUBOXONE® (buprenorphine and naloxone) Sublingual Film (CIII)  
IMPORTANT SAFETY INFORMATION**

**What is the most important information I should know about SUBOXONE Sublingual Film?**

Keep SUBOXONE Sublingual Film in a secure place out of sight and reach of children, and in a location not accessible by others, including visitors to the home. Accidental use by a child is a medical emergency and can result in death. If a child accidentally takes SUBOXONE Sublingual Film, get emergency help or call 911 right away. Tell your healthcare provider if you are living in a household where there are small children.

SUBOXONE Sublingual Film contains an opioid medicine called buprenorphine 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, a medicine available to patients for emergency treatment of an opioid overdose, including accidental use of SUBOXONE Sublingual Film 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.

SUBOXONE Sublingual Film can 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 SUBOXONE Sublingual Film with certain medicines. Taking SUBOXONE Sublingual Film 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”) SUBOXONE Sublingual Film.** Injecting SUBOXONE Sublingual Film may cause life-threatening infections and other serious health problems. Injecting SUBOXONE Sublingual Film may cause sudden serious withdrawal symptoms such as pain, cramps, vomiting, diarrhea, anxiety, sleep problems, and cravings.

**Do not switch from SUBOXONE Sublingual Film to other medicines that contain buprenorphine** without talking with your healthcare provider. The amount of buprenorphine in a dose of SUBOXONE Sublingual Film is not the same as in other medicines that contain buprenorphine. Your healthcare provider will prescribe a starting dose of SUBOXONE Sublingual Film that may be different than other buprenorphine containing medicines you may have been taking.

Do not stop taking SUBOXONE Sublingual Film 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 SUBOXONE Sublingual Film.

Never give anyone else your SUBOXONE Sublingual Film. They could die from taking it. Selling or giving away SUBOXONE Sublingual Film is against the law.

Death has been reported in those who are not opioid dependent.

**Who should not take SUBOXONE Sublingual Film?**

**Do not take SUBOXONE Sublingual Film** if you are allergic to buprenorphine or naloxone.

Do not take SUBOXONE Sublingual Film before the effects of other opioids (e.g., heroin, hydrocodone, methadone, morphine, oxycodone) have started to wear off as you may experience withdrawal symptoms.

**Before taking SUBOXONE Sublingual Film, 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 gland (men)
- problems urinating
- liver, kidney, or gallbladder problems
- alcoholism
- a head injury or brain problem
- mental health problems
- adrenal gland or thyroid gland problems
- tooth problems, including a history of cavities

**Tell your healthcare provider if you are:**

- **pregnant or plan to become pregnant.** Opioid-dependent women on buprenorphine maintenance therapy may require additional analgesia during labor. If you take SUBOXONE Sublingual Film 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.** SUBOXONE Sublingual Film 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 SUBOXONE Sublingual Film. Monitor your baby for increased drowsiness and breathing problems if you breastfeed during treatment with SUBOXONE Sublingual Film.

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

**What should I avoid while taking SUBOXONE Sublingual Film?**

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

**What are the possible side effects of SUBOXONE Sublingual Film?**

**SUBOXONE Sublingual Film can cause serious side effects, including:**

- **Trouble breathing.** Taking SUBOXONE Sublingual Film with other opioid medicines, 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 dependency or abuse.** SUBOXONE Sublingual Film can be abused in a manner similar to other opioids, legal or illicit.
- **Liver problems.** Call your healthcare provider right away if you notice any of these symptoms:
  - your skin or the white part of your eyes turning yellow (jaundice)
  - dark or “tea-colored” urine
  - light colored stools (bowel movements)
  - loss of appetite
  - pain, aching, or tenderness on the right side of your stomach area
  - nausea
- Your healthcare provider should do blood tests to check your liver before you start taking and while you take SUBOXONE Sublingual Film.
- **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:
  - shaking
  - sweating more than normal
  - feeling hot or cold more than normal
  - runny nose
  - watery eyes
  - goose bumps
  - diarrhea
  - vomiting
  - muscle aches
- **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 SUBOXONE Sublingual Film include:**
  - headache
  - nausea
  - vomiting
  - constipation
  - pain
  - increased sweating
  - decrease in sleep (insomnia)
- SUBOXONE 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. Call your healthcare provider for medical advice about side effects.

**To report pregnancy or side effects associated with taking SUBOXONE Sublingual Film, please call 1-877-782-6966. You are encouraged to report negative side effects of drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.**

For more information about SUBOXONE Sublingual Film, see the full [Prescribing Information](#), and [Medication Guide](#) or talk to your healthcare provider. For REMS information visit [www.BTODREMS.com](http://www.BTODREMS.com).