

SUBOXONE® (buprenorphine and naloxone) sublingual film (CIII)
IMPORTANT SAFETY INFORMATION

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

Keep SUBOXONE Film 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 SUBOXONE Film, get emergency help right away.

SUBOXONE Film can cause serious and life-threatening breathing problems. Call your healthcare provider 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.

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

SUBOXONE sublingual film contains an opioid that can cause physical dependence with chronic use.

- Do not stop taking SUBOXONE sublingual film without talking to your healthcare provider. 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. Your healthcare provider can tell you more about the differences between physical dependence and drug addiction.
- SUBOXONE Film is not for occasional or “as needed” use.

Life-threatening breathing problems, an overdose and even death can happen if you take benzodiazepines, sedatives, tranquilizers, antidepressants, or alcohol while using SUBOXONE Film. Ask your healthcare provider what you should do if you are taking one of these.

Call your healthcare provider 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”) SUBOXONE Film.

- Injecting SUBOXONE Film may cause death, overdose, life-threatening breathing problems or infections and other serious health problems.
- Injecting SUBOXONE Film may cause serious withdrawal symptoms such as pain, cramps, vomiting, diarrhea, anxiety, sleep problems, and cravings.

In an emergency, have family members tell emergency department staff that you are physically dependent on an opioid and are being treated with SUBOXONE Film.

SUBOXONE film 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 SUBOXONE sublingual film in a safe place to protect it from theft. Never give your SUBOXONE sublingual film to anyone else; it can cause death or harm them. Selling or giving away this medicine is against the law.

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

Do not take SUBOXONE Film if you are allergic to buprenorphine or naloxone, as serious negative effects, including anaphylactic shock, have been reported.

Do not take SUBOXONE 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.

SUBOXONE Film may not be right for you. Before taking SUBOXONE Film, tell your healthcare provider about all of your medical conditions, including:

- Liver or kidney problems
- Trouble breathing or lung problems
- An enlarged prostate gland (men)
- A head injury or brain problem
- Problems urinating
- A curve in your spine that affects your breathing (scoliosis)
- Gallbladder problems
- Adrenal gland problems
- Addison's disease
- Low thyroid hormone levels (hypothyroidism)
- A history of alcoholism
- Mental problems such as hallucinations (seeing or hearing things that are not there)
- Are pregnant or plan to become pregnant. Opioid-dependent women on buprenorphine maintenance therapy may require additional analgesia during labor. If you take SUBOXONE Film while pregnant, your baby may have signs of opioid withdrawal at birth. Neonatal opioid withdrawal syndrome (NOWS) is an expected and treatable outcome of prolonged use of opioids during pregnancy. Talk to your healthcare provider if you are pregnant or plan to become pregnant.

- Are breastfeeding or plan to breastfeed. The active ingredients of SUBOXONE Film can pass into your milk and may harm your baby. Talk with your healthcare provider about the best way to feed your baby during treatment with SUBOXONE Film. Watch your baby for increased drowsiness and breathing problems.

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

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

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 while using SUBOXONE Film until you have talked with your healthcare provider.

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

What should I avoid while taking SUBOXONE Film?

- **Do not drive, operate heavy machinery, or perform any other dangerous activities until you know how this medicine 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 SUBOXONE Film.
- **You should not drink alcohol** while using SUBOXONE Film, as this can lead to loss of consciousness or even death.

What are the possible side effects of SUBOXONE Film?

SUBOXONE Film can cause serious side effects, including:

- **Respiratory problems.** You have a higher risk of death and coma if you take SUBOXONE Film with other medicines, such as benzodiazepines.
- **Sleepiness, dizziness, and problems with coordination.**

- **Dependency or abuse.** SUBOXONE 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 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
 - you have stomach (abdomen) pain or nausea

Your healthcare provider should do tests before you start taking and while you take SUBOXONE Film.

- **Allergic reaction.** You may have a rash, hives, swelling of the face, wheezing, or a loss of blood pressure and consciousness. Call a healthcare provider 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 healthcare provider 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 SUBOXONE Film 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 healthcare provider about any side effect that bothers you or that does not go away.

- Long-term (chronic) use of opioids, including SUBOXONE, may cause fertility problems 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 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 or call 1-800-FDA-1088.

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