

Taking SUBOXONE[®] Sublingual Film

- Always take SUBOXONE (buprenorphine and naloxone) Sublingual Film (CIII) exactly as prescribed by your doctor
- Before taking SUBOXONE Film(s), it's a good idea to drink some water to moisten your mouth. This should help the film(s) dissolve more easily
- Make sure your hands are dry. SUBOXONE Film should be held between 2 fingers by the outside edges of the film
- SUBOXONE Film should be placed under your tongue (close to the base on either side)
- The medication in SUBOXONE Film is absorbed into the bloodstream through blood vessels under your tongue



When placing SUBOXONE Sublingual Film(s) under your tongue:

- Place the SUBOXONE Film under your tongue (close to the base on either side)
 - If you are directed to use 2 films at a time, place the other film under your tongue on the opposite side at the same time. Try to avoid having the films touch as much as possible
 - Keep the films in place until they are completely dissolved
 - If you are directed to use a third film, place it under your tongue on either side immediately after the first 2 have dissolved
- While SUBOXONE Film is dissolving, don't chew or swallow the sublingual films because less will be absorbed into your bloodstream and it will not work as well
 - Talking while the films are dissolving can interfere with how well the medication in SUBOXONE Film is absorbed

Suboxone[®] *Sublingual Film*
(buprenorphine and naloxone)  *Film*

Important Safety Information:

SUBOXONE® (buprenorphine and naloxone) Sublingual Film (CIII) is indicated for maintenance treatment of opioid dependence as part of a complete treatment plan to include counseling and psychosocial support. Treatment should be initiated under the direction of physicians qualified under the Drug Addiction Treatment Act.

SUBOXONE Sublingual Film should not be used by patients hypersensitive to buprenorphine or naloxone.

SUBOXONE Sublingual Film can be abused in a manner similar to other opioids, legal or illicit. Clinical monitoring appropriate to the patient's level of stability is essential.

Chronic use of buprenorphine can cause physical dependence. A sudden or rapid decrease in dose may result in an opioid withdrawal syndrome that is typically milder than seen with full agonists and may be delayed in onset.

SUBOXONE Sublingual Film can cause serious life-threatening respiratory depression and death, particularly when taken by the intravenous (IV) route in combination with benzodiazepines or other central nervous system (CNS) depressants (ie, sedatives, tranquilizers, or alcohol). It is extremely dangerous to self-administer nonprescribed benzodiazepines or other CNS depressants while taking SUBOXONE Sublingual Film. Dose reduction of CNS depressants, SUBOXONE Sublingual Film, or both when both are being taken should be considered.

Liver function should be monitored before and during treatment.

Death has been reported in nontolerant, nondependent individuals, especially in the presence of CNS depressants.



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Children who take SUBOXONE Sublingual Film can have severe, possibly fatal, respiratory depression. Emergency medical care is critical. Keep SUBOXONE Sublingual Film out of the sight and reach of children.

Intravenous misuse or taking SUBOXONE Sublingual Film before the effects of full-agonist opioids (eg, heroin, hydrocodone, methadone, morphine, oxycodone) have subsided is highly likely to cause opioid withdrawal symptoms.

Neonatal withdrawal has been reported. Use of SUBOXONE Sublingual Film in pregnant women or during breast-feeding should only be considered if the potential benefit justifies the potential risk. Caution should be exercised when driving vehicles or operating hazardous machinery, especially during dose adjustment.

Adverse events commonly observed with the sublingual administration of SUBOXONE Sublingual Film are numb mouth, sore tongue, redness of the mouth, headache, nausea, vomiting, sweating, constipation, signs and symptoms of withdrawal, insomnia, pain, swelling of the limbs, disturbance of attention, palpitations, and blurred vision.

Cytolytic hepatitis, jaundice, and allergic reactions, including anaphylactic shock, have been reported.

This is not a complete list of potential adverse events associated with SUBOXONE Sublingual Film. Please see full Prescribing Information for a complete list.

To report an adverse event associated with taking SUBOXONE Sublingual Film, please call 1-877-782-6966. You are encouraged to report adverse events of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Suboxone® Sublingual
(buprenorphine and naloxone)  **Film**

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For complete details about SUBOXONE Sublingual Film, please see the full Product Information available at suboxone.com