Important Safety Information

INDICATION

SUBOXONE® (buprenorphine and naloxone) Sublingual Film (CIII) is a prescription medicine indicated for treatment of opioid dependence and should be used 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.

IMPORTANT SAFETY INFORMATION

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

SUBOXONE Sublingual Film can be abused in a manner similar to other opioids, legal or illicit.

SUBOXONE Sublingual Film contains buprenorphine, an opioid that can cause physical dependence with chronic use. Physical dependence is not the same as addiction. Your doctor can tell you more about the difference between physical dependence and drug addiction. Do not stop taking SUBOXONE Sublingual Film suddenly without talking to your doctor. You could become sick with uncomfortable withdrawal symptoms because your body has become used to this medicine.

SUBOXONE Sublingual Film can cause serious life-threatening breathing problems, overdose and death, particularly when taken by the intravenous (IV) route in combination with benzodiazepines or other medications that act on the nervous system (ie, sedatives, tranquilizers, or alcohol). It is extremely dangerous to take nonprescribed benzodiazepines or other medications that act on the nervous system while taking SUBOXONE Sublingual Film.

You should not drink alcohol while taking SUBOXONE Sublingual Film, as this can lead to loss of consciousness or even death.

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

Your doctor may monitor liver function before and during treatment.

SUBOXONE Sublingual Film is not recommended in patients with severe hepatic impairment and may not be appropriate for patients with moderate hepatic impairment. However, SUBOXONE Sublingual Film may be used with caution for maintenance treatment in patients with moderate hepatic impairment who have initiated treatment on a buprenorphine product without naloxone.

Keep SUBOXONE Sublingual Film out of the sight and reach of children. Accidental or deliberate ingestion of SUBOXONE Sublingual Film by a child can cause severe breathing problems and death.

Do not take SUBOXONE Sublingual Film before the effects of other opioids (eg, heroin, hydrocodone, methadone, morphine, oxycodone) have subsided as you may experience withdrawal symptoms.

Injecting SUBOXONE may cause serious withdrawal symptoms such as pain, cramps, vomiting, diarrhea, anxiety, sleep problems, and cravings.

Before taking SUBOXONE Sublingual Film, tell your doctor if you are pregnant or plan to become pregnant. If you are pregnant or become pregnant while taking SUBOXONE Sublingual Film, alert your doctor immediately and you should report it using the contact information provided below.*

Neonatal withdrawal has been reported following the use of buprenorphine by the mother during pregnancy.

Before taking SUBOXONE Sublingual Film, talk to your doctor if you are breastfeeding or plan to breastfeed your baby. SUBOXONE can pass into your breast milk. You and your doctor should consider the development and health benefits of b eastfeeding along with your clinical need for SUBOXONE Sublingual Film and should also consider any potential adverse effects on the breastfed child from the drug or from the underlying maternal condition.

Do not drive, operate heavy machinery, or perform any other dangerous activities until you know how SUBOXONE Sublingual Film affects you. Buprenorphine in SUBOXONE Sublingual Film can cause drowsiness and slow reaction times during dose-adjustment periods.

Common side effects of SUBOXONE Sublingual Film include nausea, vomiting, drug withdrawal syndrome, headache, sweating, numb mouth, constipation, painful tongue, redness of the mouth, intoxication (feeling lightheaded or drunk), disturbance in attention, irregular heartbeat, decrease in sleep, blurred vision, back pain, fainting, dizziness, and sleepiness.

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

For more information about SUBOXONE Sublingual Film or SUBOXONE® (buprenorphine and naloxone) Sublingual Tablet (CIII), please see full Prescribing Information and Medication Guide at www.SuboxoneREMS.com.

Please see full Prescribing Information.

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Reckitt Benckiser Pharmaceuticals Inc.

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Suboxone® *Sublingual Film*
(buprenorphine and naloxone) CIII
2 mg/0.5 mg • 4 mg/1 mg • 8 mg/2 mg • 12 mg/3 mg