

**SUBOXONE® (buprenorphine and naloxone) Sublingual Film (CIII)—
Approved for use in both induction and maintenance treatment
of opioid dependence in appropriate patients*¹**

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.

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.

Buprenorphine/naloxone products are not recommended in patients with severe hepatic impairment and may not be appropriate for patients with moderate hepatic impairment. Buprenorphine/naloxone drug products are not recommended for induction in patients with moderate hepatic impairment due to the increased risk of precipitated withdrawal. However, buprenorphine/naloxone products may be used with caution for maintenance treatment in patients with moderate hepatic impairment who have initiated treatment on a buprenorphine product without naloxone.¹

Data from 2000-2010 show a more than 5-fold increase in non-heroin opioid-abuse treatment admissions in ages 12 and older.² Introduced in 2010 by Reckitt Benckiser Pharmaceuticals Inc., SUBOXONE Film delivers buprenorphine and naloxone through a film formulation. Buprenorphine has been shown to be effective for treating opioid dependence in double-blind clinical trials.^{3,4} The buprenorphine component of SUBOXONE Film may reduce subjective opioid cravings.^{4,5} The naloxone component has no clinical effect when administered by the sublingual route because of low sublingual bioavailability, and may help mitigate misuse or abuse by deterring intravenous use of the medication in individuals dependent on full opioid agonists.^{1,6,7}

In addition, SUBOXONE Film:

- **May help with continuity of treatment for appropriate patients***— Prior to induction, consideration should be given to the type of opioid dependence (long- or short-acting opioid products), the time of the last opioid use, and the degree or level of opioid dependence. With its approval for both induction and maintenance phases of treatment in appropriate patients,* SUBOXONE Film may allow patients dependent on short-acting opioids to transition between opioid dependence treatment phases (induction through maintenance) with no changes in medication form or formulation.¹ (For patients taking long-acting opioids, induction with buprenorphine monotherapy is recommended when used according to approved administration instructions. When the long-acting opioid is used, dosage adjustments may be necessary when transitioning from induction with buprenorphine to maintenance treatment with a buprenorphine and naloxone combination product.)¹ Patients being switched between buprenorphine and naloxone or buprenorphine only sublingual tablets and SUBOXONE Sublingual Film should be started on the corresponding dosage of the previously administered product. However, dosage adjustments may be necessary when switching between products. Not all strengths and combinations of the SUBOXONE Sublingual Films are bioequivalent to the SUBOXONE® (buprenorphine and naloxone) sublingual tablets as observed in pharmacokinetic studies. Therefore, systemic exposures of buprenorphine and naloxone may be different when patients are switched from tablets to film or vice versa. Patients should be monitored for symptoms related to overdosing or underdosing.¹
- **Provides flexible dosing options**—SUBOXONE Film is available in a variety of dosage strengths: 2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg, and 12 mg/3 mg of buprenorphine and naloxone.¹ On Day 1 of induction, a total daily dosage of up to 8 mg/2 mg SUBOXONE Film is recommended. Clinicians should start the induction phase of treatment with an initial dose of 2 mg/0.5 mg or 4 mg/1 mg buprenorphine/naloxone and may titrate upward in 2- or 4-mg increments of buprenorphine, at approximately 2-hour intervals, under supervision, to 8 mg/2 mg buprenorphine/naloxone based on the control of acute withdrawal symptoms. On Day 2 of induction, a single daily dose target of up to 16 mg/4 mg SUBOXONE Film is recommended. It is recommended that an adequate maintenance dose, titrated to clinical effectiveness, be achieved as rapidly as possible.¹
- **Features child-resistant packaging**—Each SUBOXONE Film comes in a unit-dose child-resistant pouch.¹

Reckitt Benckiser Pharmaceuticals has been offering opioid-dependence treatment options since 2003. Its ongoing commitment to multiple stakeholders is reflected in the informational support it provides to patients, healthcare professionals, and health plans.

*For patients taking long-acting opioids, induction with buprenorphine monotherapy is recommended when used according to approved administration instructions.

Please see enclosed full Prescribing Information and following pages for Indication and Important Safety Information.

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 breastfeeding 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.

*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.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

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.SuboxoneFilmREMS.com.

Please see enclosed full Prescribing Information.

References: 1. SUBOXONE Sublingual Film [package insert]. Richmond, VA: Reckitt Benckiser Pharmaceuticals Inc.; April 2014. 2. Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. *Treatment Episode Data Set (TEDS): 2000-2010. National Admissions to Substance Abuse Treatment Services*. DASIS Series S-61, HHS Publication No. (SMA) 12-4701. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2012. 3. Johnson RE, Strain EC, Amass L. Buprenorphine: how to use it right. *Drug Alcohol Depend.* 2003;70(2):559-577. 4. Fudala PJ, Bridge TP, Herbert S, et al; for the Buprenorphine/Naloxone Collaborative Group Study. Office-based treatment of opiate addiction with a sublingual-tablet formulation of buprenorphine and naloxone. *N Engl J Med.* 2003;349(10):949-958. 5. Ling W, Amass L, Shoptaw S, et al. A multi-center randomized trial of buprenorphine-naloxone versus clonidine for opioid detoxification: findings from the National Institute on Drug Abuse Clinical Trials Network. *Addiction.* 2005;100(8):1090-1100. 6. Harris DS, Jones RT, Welm S, Upton RA, Lin E, Mendelson J. Buprenorphine and naloxone co-administration in opiate-dependent patients stabilized on sublingual buprenorphine. *Drug Alcohol Depend.* 2000;61(1):85-94. 7. Harris DS, Mendelson JE, Lin ET, Upton RA, Jones RT. Pharmacokinetics and subjective effects of sublingual buprenorphine, alone or in combination with naloxone. *Clin Pharmacokinet.* 2004;43(5):329-340.



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(buprenorphine and naloxone)  Film

