About Medication-Assisted Treatment With SUBOXONE® (buprenorphine and naloxone) Sublingual Film (CIII)

Opioid dependence, also known as opioid prescription painkiller or heroin addiction, is a chronic medical condition caused in part by changes in the brain's chemistry that can result from regular opioid drug use. Long-term use of opioids can physically transform the brain and lead to compulsive, drug-seeking behavior and dependency. As with other chronic medical conditions, opioid dependence can be successfully treated but not cured with a combination of medication and behavioral changes.

Treatment of Opioid Dependence in an Office-Based Setting

As a result of the Drug Abuse Treatment Act (DATA) 2000, patients can be discreetly prescribed a medication called buprenorphine/naloxone in the privacy of a doctor's office. Buprenorphine can help maintain patients in treatment and reduce opioid use by suppressing feelings of withdrawal and opioid cravings, and it is approved for at-home use, so patients can continue their daily activities while under a doctor's care in much the same way that other chronic diseases such as diabetes and asthma are managed. Having this option empowers individuals who may not have sought help previously to access treatment in their own communities.

Treatment with SUBOXONE (buprenorphine and naloxone) Sublingual Film

While there is no "one-size-fits-all" approach to opioid dependence treatment, more than three million Americans have been treated with the active ingredient in SUBOXONE Film, making it a trusted and proven treatment option for helping to manage this disease.

Approved by the U.S. Food and Drug Administration on August 30, 2010, SUBOXONE Film combines buprenorphine and naloxone in a 4:1 ratio of 2mg/0.5mg, 4mg/1mg, 8g/2mg and 12mg/3mg dosage formulations, respectively, providing patients and health care professionals with flexible, customized treatment options. Buprenorphine is a partial opioid aonist that strongly binds to the opioid receptors in the brain and dose-dependently blocks other opioids, such as heroin, Vicodin and OxyContin, from attaching. In doing so, the buprenorphine helps reduce opioid use and may help increase retention in treatment by helping to manage withdrawal symptoms and decrease cravings. The naloxone, an opioid antagonist, works by minimizing the attractiveness of the prescription medication for deliberate misuse and abuse. When SUBOXONE Film is taken as prescribed, the naloxone has no effect. To help decrease the risk of pediatric exposure to SUBOXONE Film, th medicine comes in child-resistant, individually wrapped packaging. SUBOXONE Film is covered by the majority of insurance plans, Medicare and Medicaid, and individuals also may be eligible for a copay savings program.

How Medication-Assisted Treatment Works

While skeptics of medication-assisted treatment may suggest it involves exchanging one drug for another, it is important to recognize that partial opioid agonists have a different

pharmacological profile than full opioid agonists providing different clinical advantages. Receptors in the brain operate much like a door with a lock. Opioid-like drugs act as the key for opioid receptors and when a full opioid agonist, such as oxycontin or heroin, attaches to those receptors, the door swings open completely, producing the full effects of the opioid (such as the feeling of being "high"), as well as the accompanying side effects. However, when a partial opioid agonist, such as buprenorphine, occupies the same receptor, it is as if the key fits the lock but opens the door less, producing a significantly diminished effect. The limited effect acts to help maintain patients in treatment and reduce opioid use by suppressing feelings of withdrawal and opioid cravings, while also blocking other opioids from attaching to the receptors and "opening the door" completely. This can allow the individual to focus on addressing other factors contributing to his or her opioid dependence rather than being distracted by withdrawal symptoms and persistent cravings.

Quality care requires a plan tailored to individual patient needs; however, studies show that combining medication-assisted treatment with counseling may increase the likelihood of success and may improve the psychosocial health of patients fighting opioid dependence. Counseling also can help patients learn how to cope with events or situations associated with past drug use and adopt skills that can help them recognize triggers and prevent relapse.

For more information about SUBOXONE (buprenorphine and naloxone) Sublingual Film, please visit www.SUBOXONE.com.

Indication

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.

Important Safety Information

SUBOXONE® (buprenorphine and naloxone) Sublingual Film should not be used by patients hypersensitive to buprenorphine or naloxone, as serious adverse reactions, including anaphylactic shock, have been reported.

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.

Important Safety Information (cont'd)

SUBOXONE (buprenorphine and naloxone) 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.

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 oral hypoesthesia, glossodynia, oral mucosal erythema, headache, nausea, vomiting, hyperhidrosis, constipation, signs and symptoms of withdrawal, insomnia, pain, and peripheral edema.

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 (buprenorphine and naloxone) Sublingual Film. Please see full Prescribing Information for a complete list at www.suboxone.com/pdfs/SuboxonePI.pdf.

Important Safety Information (cont'd)

To report an adverse event associated with taking SUBOXONE (buprenorphine and naloxone) 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.