

Suboxone[®] Sublingual (buprenorphine and naloxone) Film

*Evolving treatment, **empowering patients***

An innovation in treatment experience and convenience

Opioid dependence is a challenging and complicated condition, but it can be treated. If you're working to overcome opioid dependence, you know the experience can sometimes be overwhelming. That's why the formulation of your medication should help make your experience convenient.

Patients have shared their concerns about taking SUBOXONE[®] (buprenorphine and naloxone) sublingual tablets (CIII), such as:

- ✓ The time the tablets take to dissolve
- ✓ The difficulty of traveling with them
- ✓ Their taste

For some patients, these concerns can interfere with being able to focus on their daily treatment and work toward their treatment goals.

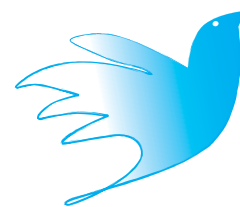
SUBOXONE Film, an improved formulation of SUBOXONE, may improve your daily treatment experience. And clinical trial patients tell us they prefer SUBOXONE Film to the SUBOXONE Tablet.^{1a}

SUBOXONE Film, an **innovation in treatment experience and convenience**, is indicated for long-term treatment of opioid dependence and should be used as part of a complete treatment plan that includes counseling and support.

SUBOXONE Film delivers:

- ✓ An evolved patient experience
 - Faster to dissolve than SUBOXONE Tablet^{1b}
 - A favorable taste rating (more than 71% of patients scored the taste as neutral or better)^{1c}
 - Individually wrapped in compact unit-dose pouches that are child-resistant^{1d} and easy to carry^{1e}
 - Once-daily dosing (just like SUBOXONE Tablet)²
 - Clinically interchangeable with SUBOXONE Tablet, so your doctor can easily transition you. Your doctor will monitor your progress to ensure your dose of SUBOXONE Film is appropriate³
- ✓ Built-in support from the online Here to Help[®] Program, designed to help you stay engaged in your treatment and focused on your goals

You should know: People who have taken buprenorphine have suffered serious breathing problems and death—especially when taking buprenorphine by injection, and in combination with benzodiazepines or other central nervous system depressants (including alcohol).





Support you need from the Here to Help® Program

The Here to Help Program is a free online personal support program, designed to work as part of your treatment with SUBOXONE® (buprenorphine and naloxone) Sublingual Film (CIII). Its unique, interactive approach—built around known factors for treatment success—can help you:

- **Get answers to important questions**—so you see opioid dependence as the chronic disease it is—and understand what that means to you
- **Choose your personal path** by focusing on the issues that are most important to you and your treatment right now, today. Simple activities help you learn to recognize issues that might put your treatment at risk, so you can make plans to interrupt early signs of trouble. If you have a setback, you can find essential guidance that could help you get back into treatment and protect your recovery
- **Improve vital skills** that could make your recovery stronger. Learn, plan, and take practical steps that could help you manage stress, handle difficult situations, think more positively, and keep making progress

Repeat activities that were especially helpful, and get e-mail guidance to help you stay motivated and engaged in treatment.

The Here to Help Program is only for people in treatment with SUBOXONE Film. [Get started now.](#)

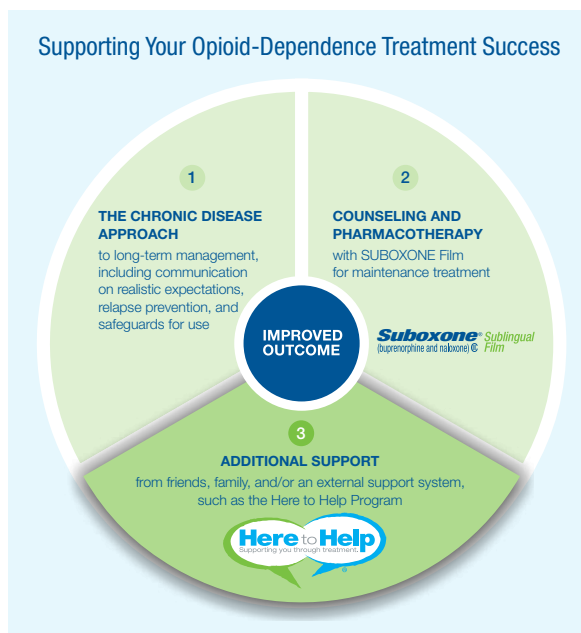
You should know: Your doctor is your best source of information about your treatment. The Here to Help Program is not a substitute for professional counseling or therapy. Having support is not a guarantee that you will meet your treatment goals.

Improve your daily treatment experience: ask your doctor about switching to SUBOXONE Film.

Keep the whole picture in mind

Opioid dependence is so much more than a medical condition: your relationships, your thoughts, and your daily routines are all tied together.⁴ Ask your doctor to help you connect with counseling. Counseling can help you learn to manage triggers and high-risk situations while you work to get your life back on track. That's why, when you combine SUBOXONE Film treatment with counseling and other forms of support, you increase the likelihood that your treatment will succeed.

The Here to Help Program was designed to go hand-in-hand with your treatment



Comparisons are between SUBOXONE® (buprenorphine and naloxone) sublingual tablets (CIII) and SUBOXONE® (buprenorphine and naloxone) Sublingual Film (CIII).

1. Data on file, Reckitt Benckiser Pharmaceuticals Inc., Richmond, VA:

- Patient preferred:** Clinical trial participants preferred SUBOXONE Film over the SUBOXONE Tablet. Results from a questionnaire collected at discharge of a 13-week, multicenter, open-label safety trial. Patients were asked, "Based on your previous experience with SUBOXONE Tablets and your current experience with SUBOXONE Film, which product do you prefer?" (n=159)
- Dissolve time:** The time required for both SUBOXONE Film and SUBOXONE Tablet dissolution is dependent on saliva quantity and is subject to individual variation, and dose and strength taken. Mean dissolution time for all doses tested (8 mg, 2 mg) was between 5 and 6.6 minutes for SUBOXONE Film and between 7 and 12.4 minutes for the SUBOXONE Tablet.
- Taste:** In a patient questionnaire, more than 71% of patients who have tried SUBOXONE Film rated the taste as neutral or better on a 10-point scale. Results from a questionnaire collected at discharge of a 13-week, multicenter, open-label safety trial. Patients were asked, "Please give this product (SUBOXONE Film) a score which shows how you would rate the flavor." 10=extremely pleasant and 1=extremely unpleasant.
- Child resistance:** Meets the Consumer Product Safety Commission's standards for child resistance. During testing, one child out of 50 was able to open 2 or more pouches. After receiving instruction, the children's ability to open the pouches increased. It is important not to open the pouches in front of children.
- Portability:** Because each unit of SUBOXONE Film is individually packaged in a compact, child-resistant pouch, it's easy to carry with you. Remember to keep this medication out of the sight and reach of children, and take your prescription label along with you. If a child takes the medication, seek emergency care.

2. SUBOXONE Sublingual Film [package insert]. Richmond, VA: Reckitt Benckiser Pharmaceuticals Inc; August 2010.

3. Data on file, Reckitt Benckiser Pharmaceuticals Inc., Richmond, VA.

4. Center for Substance Abuse Treatment. *Matching Treatment to Patient Needs in Opioid Substitution Therapy*. Treatment Improvement Protocol Series 20. Publication No. (SMA) 95-3049. Rockville, MD: Substance Abuse and Mental Health Services Administration; 1995.

Please see full Product Information and Medication Guide for SUBOXONE Film
For more about SUBOXONE Tablet, please see full Product Information

Suboxone® Sublingual Film
(buprenorphine and naloxone) 

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® (buprenorphine HCl/naloxone HCl dihydrate sublingual tablets) (CIII) is indicated for the treatment of opioid dependence.

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

SUBOXONE Sublingual Film and SUBOXONE Sublingual Tablets 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 and SUBOXONE Sublingual Tablets 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 or SUBOXONE Sublingual Tablets. Dose reduction of CNS depressants, SUBOXONE Sublingual Film and SUBOXONE Sublingual Tablets, 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 or SUBOXONE Sublingual Tablets can have severe, possibly fatal, respiratory depression. Emergency medical care is critical. Keep SUBOXONE Sublingual Film and SUBOXONE Sublingual Tablets out of the sight and reach of children.

Intravenous misuse or taking SUBOXONE Sublingual Film or SUBOXONE Sublingual Tablets 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 or SUBOXONE Sublingual Tablets 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 during clinical trials and postmarketing experience for SUBOXONE Sublingual Tablets are headache, nausea, vomiting, sweating, constipation, signs and symptoms of withdrawal, insomnia, pain, and swelling of the limbs.

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 and SUBOXONE Sublingual Tablets. Please see full Product Information for a complete list.

To report an adverse event associated with taking SUBOXONE Sublingual Film or SUBOXONE Sublingual Tablets, 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.

Please see full Product Information and Medication Guide for SUBOXONE Film

For more about SUBOXONE Tablet, please see full Product Information

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



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