

Evolving treatment, empowering patients

### Switching to SUBOXONE Film

Ask your doctor whether you may improve your daily treatment experience by switching to SUBOXONE Film. SUBOXONE Film delivers:

- An evolved patient experience
  - Faster to dissolve than SUBOXONE® (buprenorphine and naloxone) sublingual tablets (CIII)¹b
  - A favorable taste rating (more than 71% of patients scored the taste as neutral or better)<sup>1c</sup>
  - Individually wrapped in compact unit-dose pouches that are child-resistant<sup>1d</sup> and easy to carry<sup>1e</sup>
  - Once-daily dosing (just like SUBOXONE Tablet)<sup>2</sup>
  - 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 appropriate<sup>3</sup>
- ✓ 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).

#### Some things to keep in mind:

- 1. You'll need a new prescription to switch to SUBOXONE Film.
- 2. SUBOXONE Film comes in the same dosage strengths as SUBOXONE Tablet.
- 3. If you're currently taking SUBOXONE Tablet, you will not need to repeat your induction to switch to SUBOXONE Film.
- 4. Ask your doctor or other healthcare professional how to take SUBOXONE Film. Once you have your prescription, be sure you read the Medication Guide and get any questions you may have answered.
- 5. Treatment that includes SUBOXONE Film can help you stay in treatment and reduce illicit opioid use by suppressing withdrawal symptoms and reducing cravings—so you can focus on rebuilding your life and get back to the things you care about.

You should know: Long-term use of SUBOXONE Film causes physical dependence. Never stop taking SUBOXONE Film without first talking with your doctor. If you abruptly stop treatment with SUBOXONE Film, or reduce the amount you take too quickly, you could experience withdrawal symptoms.



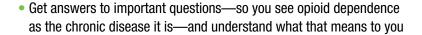


#### An innovation in treatment experience and convenience

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.

## Support you need with 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 plan with SUBOXONE® (buprenorphine and naloxone) Sublingual Film (CIII). Its unique, interactive approach—built around known factors for treatment success—can help 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.

# Ask your doctor about switching to SUBOXONE Film, an improved formulation of SUBOXONE that may improve your daily treatment experience. And be sure to discuss the Medication Guide.

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:
  - a. 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)
  - b. 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.
  - c. *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.
  - d. 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.
  - e. 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.



## **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 HCI/naloxone HCI 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



