SUBOXONE® (buprenorphine and naloxone) Sublingual Film (CIII)
Authorized Generic of SUBOXONE® (buprenorphine and naloxone) Sublingual Film (CIII)
SUBOXONE® (buprenorphine and naloxone) Sublingual Tablet (CIII)
SUBUTEX® (buprenorphine) Sublingual Tablet (CIII)

Risk Evaluation and Mitigation Strategy (REMS)

What is the SUBOXONE Film, AUTHORIZED GENERIC OF SUBOXONE® Film, SUBOXONE Tablets, and SUBUTEX Tablets REMS?

The Food and Drug Administration (FDA) has required a Risk Evaluation and Mitigation Strategy (REMS) for SUBOXONE Film, the Authorized Generic of SUBOXONE Film, SUBOXONE Tablets, and SUBUTEX Tablets. A REMS is a strategy to mitigate known or potential serious risks associated with a drug product and is required by the FDA to ensure that the benefits of a drug outweigh its risks.

The purpose of the SUBOXONE Film, the Authorized Generic of SUBOXONE Film, SUBOXONE Tablet, and SUBUTEX Tablet REMS program is to inform healthcare professionals and patients about the safe use conditions and serious risks, including accidental overdose, misuse, and abuse, associated with buprenorphine-containing transmucosal products indicated for the treatment of opioid dependence.

What products are covered under SUBOXONE Film, AUTHORIZED GENERIC OF SUBOXONE® Film, SUBOXONE Tablets, and SUBUTEX Tablets?

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The use of buprenorphine-containing products should be part of a comprehensive treatment plan to include counseling and psychosocial support. Treatment must be initiated under the direction of prescribers qualified under the Drug Addiction Treatment Act of 2000.

Where can I obtain additional information?

Please see the Prescribing Information and Medication Guides for all four buprenorphine-containing products.

For more information about SUBOXONE Film, AUTHORIZED GENERIC OF SUBOXONE® Film, SUBOXONE Tablets, and SUBUTEX Tablets, including all program materials and instructions call 1-866-463-4846 or visit www.SuboxoneREMS.com

General information about buprenorphine treatment and the treatment of addiction are available through numerous sources, including but not limited to:

- SAMHSA website (*www.samhsa.gov/medication-assisted-treatment*)
- American Society of Addiction Medicine website (*www.asam.org*)
- American Academy of Addiction Psychiatry website (*www.aaap.org*)

To report SUSPECTED ADVERSE EVENTS, contact:

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- FDA MedWatch program by phone at 1-800-FDA-1088 or online at www.fda.gov/medwatch/report.htm

Materials for Prescribers:

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Where can I obtain additional information?

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Prescribers

Prescribers play an important role in reducing the risks of accidental overdose, misuse, and abuse, associated with buprenorphine-containing transmucosal products. To help mitigate these risks, prescribers should:

- **Verify** the patient meets appropriate diagnostic criteria.
- **Check** state Prescription Drug Monitoring Programs, where practical, to identify behaviors that may represent abuse and review all medications (e.g., benzodiazepines, other opioids, and CNS depressants) to assess for appropriateness of co-prescribing.
- **Discuss the risks** (including misuse and abuse) **and side effects** associated with buprenorphine-containing products, including those described in the Medication Guide (See the brochure, ***Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Prescribers*** for important safety information regarding these risks).
- **Explain** what patients should do if they experience side effects.
- **Provide induction** doses under appropriate supervision.
- **Prescribe a limited amount** of medication to the patient that will last until the next visit.
- **Explain** how to safely store the medication out of sight and reach of all others, especially children.
- **Schedule** patient appointments commensurate with patient stability (weekly or more frequent visits recommended for the first month).
- **Consider** "pill/film count/dose" reconciliation.
- **Assess**:
  - whether patient is receiving counseling/psychosocial support considered necessary for treatment **and if not, encourage them to do so**.
  - whether patient is making progress toward treatment goals (including, as appropriate, urine toxicology testing).
  - the appropriateness of maintenance dose.
  - whether or not benefits of treatment outweigh the risks.

To prescribe products covered under the SUBOXONE Film, the Authorized Generic of SUBOXONE Film, SUBOXONE Tablets, and SUBUTEX Tablets REMS, a prescriber must be certified to treat opioid dependence under the Drug Addiction Treatment Act of 2000 (DATA 2000). For certification information, click here.

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Pharmacists

Pharmacists play an important role in reducing the risks of accidental overdose, misuse, and abuse, associated with buprenorphine-containing transmucosal products. To help mitigate these risks, pharmacists should:

- **Verify** that the prescription you receive is from a prescriber who is in compliance with the provisions of the Drug Addiction Treatment Act of 2000 (DATA 2000).
- Keep in mind that a **limited supply of buprenorphine-containing products should be dispensed** during the initiation of therapy. This is due to the need for prescribers to closely and frequently assess the patients' needs, their symptoms, and potential risk of misuse, diversion, and abuse.
- **Check** state Prescription Drug Monitoring Programs, where practical, to identify behaviors that may represent abuse and review all medications (e.g., benzodiazepines, other opioids, and CNS depressants) to assess for appropriateness of co-prescribing.
- **Provide the Medication Guide to patients** each time the medicine is dispensed and discuss the risks and side effects associated with buprenorphine products, including what to do if patients experience side effects.
- **Remind** patients who are picking up induction doses to return as directed to the doctor's office so that they can be supervised while taking the medication.
- **Explain** how to safely store the medication out of the sight and reach of all others, especially children.
- Provide appropriate patient counseling on safe use of buprenorphine-containing products and **encourage patients to seek psychosocial counseling and support for safe and effective treatment.**
- **Be vigilant** in detecting fraudulent prescriptions or simultaneous prescriptions for the same patient from multiple prescribers.
- **Review** the brochure ***Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Pharmacists*** for additional information.

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Educating Patients

The SUBOXONE Film, the Authorized Generic of SUBOXONE Film, SUBOXONE Tablet, and SUBUTEX Tablet Medication Guides are a core component of the REMS program. Each respective Medication Guide contains important information about the product, including proper administration, potential adverse events, and other precautions.

You should review the medication guide with patients for whom you prescribe SUBOXONE Film, the Authorized Generic of SUBOXONE Film, SUBOXONE Tablet, or SUBUTEX Tablet to ensure that they understand the proper use and safety precautions associated with these products. You have received a tear pad with medication guides that you can distribute to patients. If you require additional copies of the medication guide, you can request them through your Clinical Liaison or by calling 1-866-463-4846.

Additionally, tear pads of the medication guides are provided to pharmacies that order and dispense SUBOXONE Film, the Authorized Generic of SUBOXONE Film, SUBOXONE Tablet or SUBUTEX Tablet with reminders that they should provide the correct Medication Guide with every prescription.

Communicate the following **messages** to patients about **the serious risks of accidental overdose, misuse, and abuse**:

- **Instruct patients to keep these products in a secure place, out of the sight and reach of all others, especially children. Accidental or deliberate ingestion by a child may cause respiratory depression that can result in death. If a child is exposed to one of these products, medical attention should be sought immediately.**
- Warn patients that it is extremely dangerous to self-administer non-prescribed benzodiazepines or other central nervous system (CNS) depressants (including alcohol) while taking these products. Caution patients prescribed benzodiazepines or other CNS depressants to use them only as directed by their prescriber.
- Instruct patients never to give these products to anyone else, even if he or she has the same signs and symptoms. They may cause harm or death.
- Advise patients that these products contain an opioid that can be a target for people who abuse prescription medications or street drugs.
- Advise patients that selling or giving away these products is against the law.
- **Use the contents of each drug product's Medication Guide**, in its entirety, with each patient to review the information noted above, including side effects and what to do if a patient has them. The Medication Guide will be dispensed with each prescription for a buprenorphine-containing transmucosal product.
- **Strongly encourage patients to seek psychosocial counseling and support for safe and effective treatment.**

Additional information about safe use conditions and patient monitoring can be found in the Prescriber Brochure and in the warning and precautions sections of the product-specific Prescribing Information.

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