



FPO

<Address Area>

IMPORTANT DRUG WARNING

**Subject: Risk Evaluation and Mitigation Strategy (REMS) for
SUBOXONE® (buprenorphine and naloxone) Sublingual Film CIII
SUBOXONE® (buprenorphine and naloxone) Sublingual Tablets CIII
SUBUTEX® (buprenorphine) Sublingual Tablets CIII**

<DATE>

Dear Pharmacist:

The purpose of this letter is to inform you of a Risk Evaluation and Mitigation Strategy (REMS) for SUBOXONE sublingual film, SUBOXONE sublingual tablets, SUBUTEX sublingual tablets, and the generic equivalent products, hereafter collectively called buprenorphine-containing products. This REMS does not apply to buprenorphine-containing products that are dispensed to patients in an Opioid Treatment Program (OTP) under 42 CFR Part 8.

A REMS has been implemented as part of the FDA requirements to ensure that the benefits of treatment with buprenorphine-containing products outweigh the potential risks. Buprenorphine, like morphine and other opioids, has the potential for being abused and misused. Abuse of buprenorphine poses a risk of overdose and death. This risk is increased with the concomitant use of buprenorphine and alcohol and other central nervous system (CNS) depressants especially benzodiazepines.

SUBUTEX sublingual tablets, SUBOXONE sublingual tablets, and SUBOXONE sublingual film are partial-opioid agonists indicated for the treatment of opioid dependence. Products containing the single active ingredient buprenorphine are indicated for the treatment of opioid dependence and are preferred for induction. SUBOXONE sublingual film is one of several buprenorphine/naloxone-containing products that may be used for **induction** in patients physically dependent on heroin or other short-acting opioids. All products can be used for **maintenance**.

These products are used as part of a complete treatment plan, including counseling and psychosocial support.

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Pharmacist Action

As a pharmacist, you will play an important role in ensuring that buprenorphine-containing products are used safely and appropriately. Each time you fill a prescription for a buprenorphine-containing product, make sure to:

- Verify that the prescription you receive is from a prescriber who is in compliance with the provisions of 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 of prescribers to closely and frequently assess the patients' needs, their symptoms, and potential risk of misuse, diversion, and abuse.
- **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 reach of children.
- Provide appropriate patient counseling on the safe use of buprenorphine-containing products and **encourage patients to seek psychosocial counseling and support for safe and effective treatment.**
- Pharmacists should also check state Prescription Drug Monitoring Programs, where practical, to identify behaviors that may represent abuse. Pharmacists should be vigilant in detecting fraudulent prescriptions or simultaneous prescriptions for the same patient from multiple prescribers.

Serious Risks of Buprenorphine-containing Products

The following key messages need to be communicated to patients about safe use of products covered under the REMS to mitigate **the serious risks of accidental overdose, misuse and abuse:**

- **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.**
- Advise patients that these products contain an opioid that can be a target for people who abuse prescription medications or street drugs. Caution patients to keep their products in a safe and secure place, out of the reach of children, and to protect them from theft.
- Warn patients that it is extremely dangerous to self-administer non-prescribed benzodiazepines or other central nervous system (CNS) depressants (including alcohol) with these products. Caution patients prescribed benzodiazepines or other CNS depressants to use them only as directed by their prescriber.
- 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 counselling and support for safe and effective treatment.**

Medication Guide

- As part of the REMS, pharmacists dispensing buprenorphine-containing products for opioid dependence must supply a Medication Guide for the buprenorphine-containing product with each prescription. The Medication Guide will be provided with the product and is also available by going online to www.suboxonerems.com or by calling **1-866-463-4846**.

Reporting Adverse Events

To report SUSPECTED ADVERSE EVENTS contact:

- Indivior Inc. at 1-877-782-6966 or
- FDA MedWatch program by phone at 1-800-FDA-1088 or online at www.fda.gov/medwatch/report.htm

This letter is not a comprehensive description of the risks associated with the use of buprenorphine-containing products. Additional important safety information can be found in the ***Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Pharmacists*** educational brochure and the Prescribing Information.

Additional copies of the educational brochure, Prescribing Information, and Medication Guide for each product covered under the SUBOXONE sublingual film, SUBOXONE sublingual tablets, and SUBUTEX sublingual tablets REMS, can be obtained at www.suboxonerems.com, <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm> or by contacting the toll-free call center at **1-866-463-4846**.

Sincerely,

<NAME>

<TITLE>

Indivior Inc.

Enclosures:

Pharmacist Brochure: *Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Pharmacists*

