

Home

Prescribers

Pharmacists

Educating Patients

[SUBOXONE® \(buprenorphine and naloxone\) Sublingual Film \(CIII\)](#)
[SUBOXONE® \(buprenorphine and naloxone\) Sublingual Tablet \(CIII\)](#)
[SUBUTEX® \(buprenorphine\) Tablet \(CIII\)](#)

Risk Evaluation and Mitigation Strategy (REMS)

What is the 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, 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, 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 the SUBOXONE Film, SUBOXONE Tablets, and SUBUTEX Tablets REMS?

Buprenorphine-containing products are available both as products containing the single active ingredient, buprenorphine, and products that combine buprenorphine with naloxone; both types of products are indicated for the treatment of opioid dependence.

The following products are covered under the SUBOXONE Film, SUBOXONE Tablets, and SUBUTEX Tablets REMS Program:

- SUBOXONE® (buprenorphine/naloxone) sublingual film
- SUBOXONE® (buprenorphine hydrochloride/naloxone hydrochloride) sublingual tablet
- SUBUTEX® (buprenorphine hydrochloride) sublingual tablet

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 three buprenorphine-containing products.

For more information about the SUBOXONE Film, SUBOXONE Tablets, and SUBUTEX Tablets REMS, 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.dpt.samhsa.gov)
- American Society of Addiction Medicine website (www.asam.org)
- American Academy of Addiction Psychiatry website (www.aaap.org)

To report SUSPECTED ADVERSE EVENTS, contact:

- The manufacturer of the product taken or
- FDA MedWatch program by phone at 1-800-FDA-1088 or online at www.fda.gov/medwatch/report.htm

Materials for Prescribers:

[REMS Letter to Prescribers](#)
[Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Prescribers](#)
[Appropriate Use Checklist](#)

Materials for Pharmacists:

[REMS Letter to Pharmacists](#)
[Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Pharmacists](#)

Materials for Patients:

[SUBOXONE Film Med Guide](#)
[SUBOXONE Tablet Med Guide](#)
[SUBUTEX Med Guide](#)

[Privacy Policy](#) | [Terms of Use](#)

SUBOXONE® and Here to Help® are registered trademarks of Indivior UK Limited.

SUBOXONE® Film is manufactured for Indivior Inc., Richmond, VA 23235 by MonoSol Rx LLC, Warren, NJ 07059.

This site is sponsored by Indivior Inc. and intended solely for residents of the United States only.

© 2016 Indivior Inc.

XXX-XX-X-XXXX-XXXX

[SUBOXONE[®] \(buprenorphine and naloxone\) Sublingual Film \(CIII\)](#)
[SUBOXONE[®] \(buprenorphine and naloxone\) Sublingual Tablet \(CIII\)](#)
[SUBUTEX[®] \(buprenorphine\) Tablet \(CIII\)](#)

Risk Evaluation and Mitigation Strategy (REMS)

What is the 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, 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, 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 the SUBOXONE Film, SUBOXONE Tablets, and SUBUTEX Tablets REMS?

Buprenorphine-containing products are available both as products containing the single active ingredient, buprenorphine, and products that combine buprenorphine with naloxone; both types of products are indicated for the treatment of opioid dependence.

The following products are covered under the SUBOXONE Film, SUBOXONE Tablets, and SUBUTEX Tablets REMS Program:

- SUBOXONE[®] (buprenorphine/naloxone) sublingual film
- SUBOXONE[®] (buprenorphine hydrochloride/naloxone hydrochloride) sublingual tablet
- SUBUTEX[®] (buprenorphine hydrochloride) sublingual tablet

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 three buprenorphine-containing products.

For more information about the SUBOXONE Film, SUBOXONE Tablets, and SUBUTEX Tablets REMS, 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.dpt.samhsa.gov)
- American Society of Addiction Medicine website (www.asam.org)
- American Academy of Addiction Psychiatry website (www.aaap.org)

To report SUSPECTED ADVERSE EVENTS, contact:

- The manufacturer of the product taken or
- FDA MedWatch program by phone at 1-800-FDA-1088 or online at www.fda.gov/medwatch/report.htm

Materials for Prescribers:

[REMS Letter to Prescribers](#)

[Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Prescribers](#)

[Appropriate Use Checklist](#)

Materials for Pharmacists:

[REMS Letter to Pharmacists](#)

[Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Pharmacists](#)

Materials for Patients:

[SUBOXONE Film Med Guide](#)

[SUBOXONE Tablet Med Guide](#)

[SUBUTEX Med Guide](#)

[SUBOXONE® \(buprenorphine and naloxone\) Sublingual Film \(CIII\)](#)
[SUBOXONE® \(buprenorphine and naloxone\) Sublingual Tablet \(CIII\)](#)
[SUBUTEX® \(buprenorphine\) Tablet \(CIII\)](#)

Risk Evaluation and Mitigation Strategy (REMS)

What is the 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, 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, 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 the SUBOXONE Film, SUBOXONE Tablets, and SUBUTEX Tablets REMS?

Buprenorphine-containing products are available both as products containing the single active ingredient, buprenorphine, and products that combine buprenorphine with naloxone; both types of products are indicated for the treatment of opioid dependence.

The following products are covered under the SUBOXONE Film, SUBOXONE Tablets, and SUBUTEX Tablets REMS Program:

- SUBOXONE® (buprenorphine/naloxone) sublingual film
- SUBOXONE® (buprenorphine hydrochloride/naloxone hydrochloride) sublingual tablet
- SUBUTEX® (buprenorphine hydrochloride) sublingual tablet

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 three buprenorphine-containing products.

For more information about the SUBOXONE Film, SUBOXONE Tablets, and SUBUTEX Tablets REMS, 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.dpt.samhsa.gov)
- American Society of Addiction Medicine website (www.asam.org)
- American Academy of Addiction Psychiatry website (www.aaap.org)

To report SUSPECTED ADVERSE EVENTS, contact:

- The manufacturer of the product taken or
- FDA MedWatch program by phone at 1-800-FDA-1088 or online at www.fda.gov/medwatch/report.htm

Materials for Prescribers:

[REMS Letter to Prescribers](#)

[Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Prescribers](#)

[Appropriate Use Checklist](#)

Materials for Pharmacists:

[REMS Letter to Pharmacists](#)

[Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Pharmacists](#)

Materials for Patients:

[SUBOXONE Film Med Guide](#)

[SUBOXONE Tablet Med Guide](#)

[SUBUTEX Med Guide](#)



Suboxone® Sublingual Film
(buprenorphine and naloxone) ©

Suboxone®
(buprenorphine and naloxone) ©

Subutex®
(buprenorphine HCl) ©

Home

Prescribers

Pharmacists

Educating Patients

SUBOXONE® (buprenorphine and naloxone) Sublingual Film (CIII)

SUBOXONE® (buprenorphine and naloxone) Sublingual Tablet (CIII)

SUBUTEX® (buprenorphine) Tablet (CIII)

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.
- **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 additional 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 the reach of 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 the maintenance dose.
 - whether or not benefits of treatment outweigh the risks.

To prescribe products covered under the 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](#).

Materials for Prescribers:

[REMS Letter to Prescribers](#)

[Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Prescribers](#)

[Appropriate Use Checklist](#)

Materials for Pharmacists:

[REMS Letter to Pharmacists](#)

[Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Pharmacists](#)

Materials for Patients:

[SUBOXONE Film Med Guide](#)

[SUBOXONE Tablet Med Guide](#)

[SUBUTEX Med Guide](#)



[Privacy Policy](#) | [Terms of Use](#)

SUBOXONE® and Here to Help® are registered trademarks of Indivior UK Limited.

SUBOXONE® Film is manufactured for Indivior Inc., Richmond, VA 23235 by MonoSol Rx LLC, Warren, NJ 07059.

This site is sponsored by Indivior Inc. and intended solely for residents of the United States only.

© 2016 Indivior Inc.

XXX-XX-X-XXXX-XXXX

Suboxone® Sublingual Film
(buprenorphine and naloxone) ©

Suboxone®
(buprenorphine and naloxone) ©

Subutex®
(buprenorphine HCl) ©

Home

Prescribers

Pharmacists

Educating Patients

SUBOXONE® (buprenorphine and naloxone) Sublingual Film (CIII)

SUBOXONE® (buprenorphine and naloxone) Sublingual Tablet (CIII)

SUBUTEX® (buprenorphine) Tablet (CIII)

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 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.
- **Check** state Prescription Drug Monitoring Programs, where practical, to identify behaviors that may represent 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 the reach of 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.

Materials for Prescribers:

[REMS Letter to Prescribers](#)

[Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Prescribers](#)

[Appropriate Use Checklist](#)

Materials for Pharmacists:

[REMS Letter to Pharmacists](#)

[Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Pharmacists](#)

Materials for Patients:

[SUBOXONE Film Med Guide](#)

[SUBOXONE Tablet Med Guide](#)

[SUBUTEX Med Guide](#)



[Privacy Policy](#) | [Terms of Use](#)

SUBOXONE® and Here to Help® are registered trademarks of Indivior UK Limited.

SUBOXONE® Film is manufactured for Indivior Inc., Richmond, VA 23235 by MonoSol Rx LLC, Warren, NJ 07059.

This site is sponsored by Indivior Inc. and intended solely for residents of the United States only.

© 2016 Indivior Inc.

XXX-XX-X-XXXX-XXXX

Suboxone® Sublingual Film
(buprenorphine and naloxone) ©

Suboxone®
(buprenorphine and naloxone) ©

Subutex®
(buprenorphine HCl) ©

[Home](#)
[Prescribers](#)
[Pharmacists](#)
[Educating Patients](#)

[SUBOXONE® \(buprenorphine and naloxone\) Sublingual Film \(CIII\)](#)

[SUBOXONE® \(buprenorphine and naloxone\) Sublingual Tablet \(CIII\)](#)

[SUBUTEX® \(buprenorphine\) Tablet \(CIII\)](#)

Educating Patients

The [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, 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, 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 **risks of accidental overdose, misuse, and abuse**:

- 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.
- Caution patients to keep their products in a safe and secure place, out of the reach of children, and to protect them from theft.
- Advise patients that selling or giving away these products is against the law.
- **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.

Materials for Prescribers:

[REMS Letter to Prescribers](#)

[Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Prescribers](#)

[Appropriate Use Checklist](#)

Materials for Pharmacists:

[REMS Letter to Pharmacists](#)

[Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Pharmacists](#)

Materials for Patients:

[SUBOXONE Film Med Guide](#)

[SUBOXONE Tablet Med Guide](#)

[SUBUTEX Med Guide](#)



[Privacy Policy](#) | [Terms of Use](#)

SUBOXONE® and Here to Help® are registered trademarks of Indivior UK Limited.

SUBOXONE® Film is manufactured for Indivior Inc., Richmond, VA 23235 by MonoSol Rx LLC, Warren, NJ 07059.

This site is sponsored by Indivior Inc. and intended solely for residents of the United States only.

© 2016 Indivior Inc.

XXX-XX-X-XXXX-XXXX

Home

Educating Patients

SUBOXONE® (buprenorphine and naloxone) sublingual film
 SUBOXONE® (buprenorphine and naloxone) sublingual tablet
 SUBUTEX® (buprenorphine hydrochloride) sublingual tablet

Risk Evaluation and Mitigation Strategy (REMS)

You are leaving SuboxoneREMS.com

Links are provided for informational purposes only. No endorsement is made or implied. Clicking on "Continue" will take you to a website that is outside the control of Indivior Inc. You are solely responsible for your interactions with such websites.

CONTINUE → Cancel

What is the 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, 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, 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 the SUBOXONE Film, SUBOXONE Tablets, and SUBUTEX Tablets REMS?

Buprenorphine-containing products are available both as products containing the single active ingredient, buprenorphine, and products that combine buprenorphine with naloxone; both types of products are indicated for the treatment of opioid dependence.

The following products are covered under the SUBOXONE Film, SUBOXONE Tablets, and SUBUTEX Tablets REMS Program:

- SUBOXONE® (buprenorphine/naloxone) sublingual film
- SUBOXONE® (buprenorphine hydrochloride/naloxone hydrochloride) sublingual tablet
- SUBUTEX® (buprenorphine hydrochloride) sublingual tablet

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 three buprenorphine-containing products.

For more information about the SUBOXONE Film, SUBOXONE Tablets, and SUBUTEX Tablets REMS, 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.dpt.samhsa.gov)
- American Society of Addiction Medicine website (www.asam.org)
- American Academy of Addiction Psychiatry website (www.aaap.org)

To report SUSPECTED ADVERSE EVENTS, contact:

- The manufacturer of the product taken or
- FDA MedWatch program by phone at 1-800-FDA-1088 or online at www.fda.gov/medwatch/report.htm

Materials for Prescribers:

[REMS Letter to Prescribers](#)

[Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Prescribers](#)

[Appropriate Use Checklist](#)

Materials for Pharmacists:

[REMS Letter to Pharmacists](#)

[Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Pharmacists](#)

Materials for Patients:

[SUBOXONE Film Med Guide](#)

[SUBOXONE Tablet Med Guide](#)

[SUBUTEX Med Guide](#)



[Privacy Policy](#) | [Terms of Use](#)

SUBOXONE® and Here to Help® are registered trademarks of Indivior UK Limited.

SUBOXONE® Film is manufactured for Indivior Inc., Richmond, VA 23235 by MonoSol Rx LLC, Warren, NJ 07059.

This site is sponsored by Indivior Inc. and intended solely for residents of the United States only.

© 2018 Indivior Inc.

XXX-XX-X-XXXX-XXXX

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JUDITH A RACOOSIN
07/07/2016