

Risk Evaluation and Mitigation Strategy (REMS) Document

Buprenorphine-containing Transmucosal products for Opioid Dependence (BTOD) REMS Program

This REMS applies to buprenorphine-containing oral transmucosal products indicated for the treatment of opioid dependence (hereinafter, "buprenorphine-containing products"). This REMS does not apply to buprenorphine-containing products that are dispensed to patients admitted to an Opioid Treatment Program under 42 CFR Part 8.

I. Administrative Information

Initial Shared System REMS Approval: 02/2013
Most Recent REMS Update: 10/2020

II. REMS Goals

The goals of the Buprenorphine-containing Transmucosal products for Opioid Dependence (BTOD) REMS are to:

- Mitigate the risks of accidental overdose, misuse, and abuse
- Inform prescribers, pharmacists, and patients of the serious risks associated with buprenorphine-containing products

III. REMS Requirements

BTOD Applicants must ensure that prescribers and patients comply with the following requirements:

1. Prescribers who prescribe or dispense buprenorphine transmucosal products for opioid dependence (BTOD) must:

Before treatment initiation (first dose)	<ol style="list-style-type: none">1. Assess the patient's condition to verify the patient meets the diagnostic criteria for opioid dependence.2. Counsel the patient on the risks described in the Prescribing Information and Medication Guide.3. Counsel the patient on safe storage of the medication.
During treatment; at the first visit following induction	<ol style="list-style-type: none">4. Prescribe a limited amount of medication.
During treatment; at visits scheduled at intervals commensurate with patient stability	<ol style="list-style-type: none">5. Assess the patient's compliance with the prescribed medication, appropriateness of the dosage prescribed, whether patient is receiving the necessary psychosocial support, and whether patient is making adequate progress towards treatment goals.6. Counsel the patient about compliance with their medication.

1. Prescribers who prescribe or dispense buprenorphine transmucosal products for opioid dependence (BTOD) must:

7. Complete the [Appropriate Use Checklist](#). Retain a completed copy in the patient's record or by using another method (e.g. electronic health record) specific to the prescriber's office practice.
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2. Patients who are prescribed buprenorphine transmucosal products for opioid dependence:

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| Before treatment initiation | 1. Receive counseling from the prescriber on the risks and safe storage of the medication. |
| During treatment; at time intervals determined by your prescriber | 2. Be monitored for compliance with the prescribed medication, appropriateness of the dosage prescribed, assessment of whether receiving the necessary psychosocial support, and whether making adequate progress towards treatment goals. |
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To inform healthcare providers about the REMS Program and the risks and safe use of buprenorphine transmucosal products for opioid dependence, BTOD Applicants must disseminate REMS communication materials according to the table below:

Target Audience	Communication Materials & Dissemination Plan
Prescribers certified to treat opioid dependence under the Drug Addiction Treatment Act of 2000 (DATA 2000)	REMS Letter: Dear Prescriber Letter with attachments Prescriber Brochure and Appropriate Use Checklist . 1. Mail within 60 days of approval of the BTOD REMS and annually thereafter.
All prescribers certified to treat opioid dependence under DATA 2000 since the last dissemination	REMS Letter: Dear Prescriber Letter with attachments Prescriber Brochure and Appropriate Use Checklist 1. Mail monthly.
Retail pharmacies on the National Technical Information Service mailing list authorized by DEA to handle schedule III controlled substances	REMS Letter: Dear Pharmacist Letter with attachment Pharmacist Brochure . 1. Mail within 60 days of approval of the BTOD REMS and annually thereafter.

To support REMS Program operations, BTOD Applicants must:

1. Establish and maintain a REMS Program website, www.btodrems.com. The REMS Program website must include the option to print the Prescribing Information, Medication Guides, and REMS materials. All product websites for consumers and healthcare providers must include prominent REMS-specific links to the REMS Program website. The REMS Program website must not link back to the promotional product websites.
2. Make the REMS Program website fully operational and all REMS materials available through the website, BTOD REMS specialists and call center within 60 calendar days of REMS modification.
3. Establish and maintain a REMS Program call center for REMS participants at 1-855-223-3922.

To ensure REMS participants' compliance with the REMS Program, BTOD Applicants must:

4. Maintain adequate records to demonstrate that REMS requirements have been met, including, but not limited to, records of mailings and outbound calls. These records must be readily available for FDA inspections.
5. Establish a plan for addressing noncompliance with REMS Program requirements.
6. On a monthly basis, identify and attempt to contact all newly DATA 2000-certified prescribers and a random sample of existing DATA-2000 certified prescribers to create awareness of the program, confirm that REMS materials have been received, and confirm understanding of the BTOD REMS requirements.
 - a) Mail a copy of the REMS materials to prescribers who request or did not receive the REMS materials.
 - b) Provide additional follow-up information about the BTOD REMS program.
 - Option I: a live online meeting to review BTOD REMS requirements
 - Option II: a field visit to review BTOD REMS requirements
7. Monitor compliance with the prescriber requirements to document prescribing and dispensing with documentation of safe use conditions through surveys of patients and prescribers, evaluations of health care utilization databases, and ongoing surveillance (sources including, but not limited to, internet, national databases, and surveys conducted at substance abuse treatment programs).
8. Take reasonable steps to improve implementation of and compliance with the requirements in the BTOD REMS Program based on monitoring and evaluation of the BTOD REMS Program.

IV. REMS Assessment Timetable

BTOD NDA Applicants must submit REMS Assessments annually on August 30th. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. BTOD NDA Applicants must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the BTOD REMS:

Training and Education Materials

Patient

1. Medication Guide (available at www.btodrems.com)

Patient Care Form

2. [Appropriate Use Checklist](#)

Communication Materials

3. [Dear Prescriber Letter](#)
4. [Dear Pharmacist Letter](#)
5. [Prescriber Brochure: Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Prescribers](#)

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

Other Materials

7. [BTOD REMS Website \(www.btodrems.com\)](http://www.btodrems.com)