General FAQ's

What is a REMS program and what is this REMS program?

REMS stands for "Risk Evaluation and Mitigation Strategy." A REMS is a risk management program required by the U.S. Food and Drug Administration (FDA) to ensure that the benefits of a drug outweigh its risks. FDA has determined that a single, shared REMS is required for all brand and generic extended-release (ER) and long-acting (LA) opioid (narcotic) pain medicines.

What pain medicines are included in this REMS program?

The branded and generic drug products subject to this REMS program include all of the following: extended-release, oral-dosage forms containing: hydromorphone, morphine, oxycodone, oxymorphone, or tapentadol; fentanyl and buprenorphine-containing transdermal delivery systems; and methadone tablets or liquid that are indicated for use as pain medicines.

What are the goals of this REMS program?

The goal of this REMS program is to reduce serious adverse outcomes resulting from inappropriate prescribing, misuse and abuse of ER/LA opioid analgesics while maintaining patient access to pain medications. Adverse outcomes of concern include addiction, unintentional overdose, and death.

What are the components of this REMS program?

The central component of the ER/LA Opioid Analgesics REMS program is safety education/training for prescribers, patients, and their caregivers. For additional information see Prescribers, Pharmacists, and Patients FAQs on the ER/LA Opioid Analgesics REMS website at www.ER-LA-opioidREMS.com.

Who can I call if I need to speak with someone about questions I have on this REMS program?

You can call the ER/LA Opioid Analgesics REMS toll-free number at 1-800-503-0784 to speak with a call center agent who can address general questions related to this REMS program or provide assistance with navigating through this REMS website.

Who can I call if I have questions about a specific product?

You should call the ER/LA opioid analgesic company directly for product-specific questions. A listing of companies and products is on the ER/LA Opioid Analgesics REMS website available at www.ER-LA-opioidREMS.com. Click here for listing of products and company contact information.

What REMS materials are available and how can I access them?

Materials such as Medication Guides can be obtained from the following: at the pharmacy, accessed via a link on the REMS website at www.ER-LA-opioidREMS.com, or by contacting the company of the specific product directly. Additionally, the Patient Counseling Document is available on the REMS website.

What impact will this REMS program have on the healthcare system?

FDA has communicated the intent was to design and implement a REMS program without placing an unreasonable burden on the healthcare system or negatively impacting access to these necessary medications. The FDA is strongly encouraging completion of a REMS-compliant continuing education/training program by healthcare professionals in order to prescribe or dispense ER/LA opioid analgesics more safely and maintain patient access to pain medications.

How should an adverse event(s) associated with ER/LA opioid analgesics be reported?

You are strongly encouraged to report all suspected adverse reactions associated with the use of the covered ER/LA opioid analgesics by contacting either:

- the pharmaceutical company that markets the specific product (Company contact information available on the REMS website - click here for listing of products and company contact information), or
- FDA MedWatch program by phone at 1-800-FDA-1088 (1-800-332-1088) or online at www.fda.gov/medwatch/report.htm

Privacy Statement -- What happens to the information I give you?

Call Center Communicators will take steps to safeguard any information you share with us and will not intentionally otherwise use or disclose any of your personally identifiable information, except to the extent reasonably necessary: (i) to correct technical problems and malfunctions, to technically process your information and to determine the effectiveness of our projects; (ii) to protect the security and integrity of our call center; (iii) to protect our rights and property and the rights and property of others; (iv) to take precautions against liability; (v) to the extent required by law or to respond to judicial process; or (vi) to the enforcement agencies or for an investigation on a matter related to public safety or potential adverse event/product complaint, as applicable.

Does not want call recorded

This call is recorded or monitored for quality assurance. Please know that all information you provide is confidential. We apologize for the inconvenience.

Literature Request

The REMS materials can be accessed via the website at www.ER-LA-opioidREMS.com.

Confidentiality Protocol

The information that you provide to us is treated in a confidential manner. If necessary, the information may be transferred to member companies and the FDA as required by law.

Who owns this website?

The REMS Program Companies. This is a group of companies that must comply with the FDA's Risk Evaluation and Mitigation Strategy for Extended-Release and Long-Acting Opioid Analgesics.

Is this website accessible through all search engines?

This website is publicly available and should be searchable by most popular search engines.

Who do I contact if I cannot access the website?

Contact the RPC call center at 1-800-503-0784.

Why is this website required by the FDA?

This website is required by the FDA to meet the REMS requirements.

Who do I call if I have questions, comments, or concerns about this website?

Contact the RPC call center at 1-800-503-0784.

Where do I go to view the Medication Guides for the products covered under this ER/LA opioid analgesics REMS program?

The website at www.ER-LA-opioidREMS.com or call the manufacturer.

Where do I go to view the Full Prescribing Information for the products covered under this ER/LA opioid analgesics REMS program?

The website at www.ER-LA-opioidREMS.com or call the manufacturer.

How do I access, save or print any of the classwide materials on the website?

Click on the link to the material and select "print" or "save" in your web browser.

What materials are available on the website?

The REMS materials available on the website are the Patient Counseling Document, the "Dear Prescriber" letter, the PCD Order Form. The REMS website has links to other documents, such as the FDA Blueprint, specific drug US Full Prescribing Information, and specific drug medication guides.

What browsers and platforms are supported by this website?

The browsers supported by this website are Internet Explorer 8 or 9, Google Chrome v19, Safari 5, and Firefox v13. The platforms supported by this website are: Apple Mac OSX, Windows 7 PC, Android, Blackberry, iPhone OSX, and iPad OSX.

What do I do if I can't view some documents on the website?

To view the Patient Counseling Document or the "Dear Prescriber" letter, or the PCD Order Form, you need to download the Adobe Acrobat viewer. This can be found at get.adobe.com/reader.