



September 2018

FDA-Required REMS for Serious Drug Risks

Risk Evaluation and Mitigation Strategy (REMS) for opioid analgesic drug products¹ used in the outpatient setting to address their risks of misuse, abuse, addiction, and overdose.

Dear Healthcare Provider:

You are receiving this letter because you are either registered with the Drug Enforcement Administration (DEA) to prescribe Schedule II, III, IV opioid analgesics and/or you are involved in the management or support of patients with pain and their caregivers. The purpose of this letter is to inform you about the Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS) that is required by the U.S. Food and Drug Administration (FDA) for opioid analgesic drug products used in the outpatient setting, and to provide **two helpful resources** that are a part of the Opioid Analgesic REMS.

Under the conditions of the REMS, healthcare providers (HCPs) are strongly encouraged to:

- complete a REMS-compliant education program,
- counsel patients and/or their caregivers, with every prescription, on the safe use, serious risks, and proper storage and disposal of these products using the **Opioid Analgesic REMS Patient Counseling Guide** and the specific drug's **Medication Guide**, and
- consider other tools to improve patient, household, and community safety.

The Opioid Analgesic REMS Patient Counseling Guide

Enclosed with this letter is a new **Patient Counseling Guide** that was developed under the REMS. It was specifically designed to assist **you** with conducting important conversations about safety with patients for whom an opioid analgesic may be prescribed. It contains important safety information common to the drug products subject to this REMS. The **Patient Counseling Guide** should be provided to the patient or their caregiver at the time of prescribing. The **Patient Counseling Guide** is also available on the REMS website, www.opioidanalgesicrems.com, or ordered by calling the REMS Call Center at 1-800-503-0784.

REMS-compliant Accredited Continuing Education (CE): available starting in March 2019

REMS-compliant training is a critical component of the Opioid Analgesic REMS and focuses on pain management and creating a pain treatment plan. The FDA developed specific core messages to be communicated to a broad range of HCPs in the **Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain** ("FDA Blueprint"). This "FDA Blueprint," is being used to develop training that includes accredited CE courses or training offered by academic institutions/learned societies. The "FDA Blueprint" is available at: www.fda.gov/OpioidAnalgesicREMSBlueprint

Following completion of educational activities under the Opioid Analgesic REMS, HCPs should be knowledgeable about the following.

- The fundamental concepts of pain management, including definitions and mechanisms of pain
- How to assess patients in pain, identifying risk factors for abuse and addiction
- The range of therapeutic options for managing pain, including nonpharmacologic approaches and pharmacologic (non-opioid and opioid analgesics) therapies
- How to integrate opioid analgesics into a pain treatment plan individualized to the needs of the patient

- How to safely and effectively manage patients on opioid analgesics in the acute and chronic pain settings, including initiating therapy, titrating, and discontinuing use of opioid analgesics
- How to counsel patients and caregivers about the safe use of opioid analgesics, including proper storage and disposal
- How to counsel patients and caregivers about the use of naloxone for opioid overdose
- When referral to a pain specialist is appropriate
- The fundamental elements of addiction medicine
- How to identify and manage patients with opioid use disorder

REMS-compliant accredited CE will be available starting in March 2019. Visit www.opioidanalgesicrems.com for a listing of available REMS-compliant training.

Adverse Event Reporting

To report all suspected adverse reactions associated with the use of the opioid analgesics, contact:

- the FDA MedWatch program:
 - by phone at 1-800-FDA-1088 (1-800-332-1088) or
 - online at www.fda.gov/medwatch/report.htm, or
- the pharmaceutical company that markets the specific product

More information about this REMS can be obtained at: www.opioidanalgesicrems.com or by calling the Opioid Analgesic REMS Call Center at 1-800-503-0784.

Sincerely,
The Opioid Analgesic REMS Program Companies

¹ **The branded and generic drug products subject to this REMS include all:** a) oral dosage forms of extended-release and immediate-release opioids containing: codeine and codeine analogs, hydrocodone, hydromorphone, levorphanol, meperidine, morphine, oxycodone, oxymorphone, pentazocine, tapentadol and tramadol; b) fentanyl, butorphanol and buprenorphine-containing intranasal, buccal and transdermal delivery systems; and c) methadone tablets and solutions that are indicated for use as analgesics.