This guide is for pharmacists and nurses who dispense and/or administer IONSYS® (fentanyl iontophoretic transdermal system) for patient use. It includes information about the very important risk messages associated with the IONSYS Risk Evaluation and Mitigation Strategy (REMS) required by the Food and Drug Administration (FDA).

WHAT IS IONSYS?
IONSYS is an opioid analgesic that should only be used for the short-term management of acute postoperative pain severe enough to require an opioid analgesic in the hospital and for which alternative treatments are inadequate. IONSYS is a patient-controlled analgesia product that enables surgical patients to push a button to dispense fentanyl transdermally as needed for pain. Only the patient may activate IONSYS. Hospital pharmacies will not dispense IONSYS for outpatient use.

WHAT IS A REMS?
A Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage known or potential serious risks associated with a drug and is required by the US Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks.

Treatment with fentanyl, the active component of IONSYS, may result in potentially life-threatening respiratory depression and death. The Medicines Company has worked with the FDA to develop the IONSYS REMS to prevent such respiratory depression resulting from accidental exposure to persons for whom it is not prescribed.

Educating nurses, pharmacists, and other healthcare providers about the risk of respiratory depression resulting from accidental exposure associated with IONSYS and ways this risk can be mitigated is an important part of this REMS. The IONSYS REMS also requires that hospitals be certified in the IONSYS REMS Program in order to dispense IONSYS.

WHAT ARE THE ROLES OF NURSES AND PHARMACISTS IN THE SAFE USE OF IONSYS?
Hospital nurses play a critical role in ensuring the safe use of IONSYS. Before administering IONSYS, all nurses must be trained on its safe use, including its assembly, application, trouble shooting, and safe removal/disposal of IONSYS before each patient leaves the hospital. This also includes understanding that IONSYS can only be used in a hospital setting. Nurses should also be involved in educating the patient on how to use IONSYS in a safe manner, responding to alerts/notifications and alarms, ensuring proper adhesion of IONSYS, monitoring analgesic use from the digital display on the controller screen, and discontinuing/disposing IONSYS after patient use.

Pharmacists must also be trained since they will play an important role in the safe use of IONSYS. Pharmacists may be asked to take the lead in developing and implementing the processes and procedures necessary for their hospital to become certified by the IONSYS REMS Program. They may also be asked to assist in training other hospital staff in the safe use of IONSYS. Additionally, they could serve as a resource when IONSYS is implemented hospital-wide. Finally, pharmacists will order IONSYS from wholesalers, dispense them to the appropriate controlled storage locations on hospital floors, help with troubleshooting, and ensure that patients do not receive IONSYS as a medication when they leave the hospital.

Nurses and pharmacists must review this information and complete an IONSYS REMS Knowledge Assessment prior to dispensing or administering IONSYS for patient use. Hospitals will also be required to keep a record of all nurses and pharmacists who complete the knowledge assessment.
HOW CAN IONSYS BE USED SAFELY?

- Hospitals must be certified in the IONSYS REMS Program to order, dispense, and administer IONSYS
- IONSYS should only be used by patients in a hospital setting, must be discontinued prior to the patient leaving the hospital, and cannot be dispensed for use outside the hospital
- Nurses and pharmacists must review key risk messages with patients using the IONSYS Medication Guide (included with each IONSYS and as Attachment A)
  - Only the patient should administer doses from IONSYS
  - The IONSYS hydrogels should not come into contact with the patient’s fingers or mouth. Ingestion or contact with mucous membranes could lead to absorption of a potentially fatal dose of fentanyl
  - Patients should immediately inform their nurse or pharmacist if IONSYS falls off or it starts beeping
  - Patients should never leave the hospital with IONSYS
- Healthcare providers and those for whom IONSYS is not prescribed should avoid contact with the hydrogel
- Accidental exposure to an intact IONSYS or to the hydrogel component, especially by children, through contact with skin or contact with mucous membranes, can result in a fatal overdose of fentanyl

ARE THERE INSTRUCTIONS ON HOW TO USE IONSYS?

Refer to Attachment B for the IONSYS Instructions for Use and Disposal.

HEALTHCARE PROVIDER EDUCATION AND TRAINING

It is important that healthcare providers within certified hospitals are aware of the risks associated with IONSYS; and that they are properly trained on the assembly and appropriate use of IONSYS. It is also important to teach patients how to operate IONSYS to self-administer doses of fentanyl as needed to manage their acute, short-term, postoperative pain. Tools for healthcare provider training and patient training include:

IONSYS REMS MATERIALS (Available on www.IONSYSREMS.com website)


IONSYS REMS Hospital Enrollment Form: IONSYS can only be prescribed, dispensed, and administered in hospitals which are certified in the IONSYS REMS Program. Among other requirements, the hospital Authorized Representative must ensure the institution has documented processes in place to ensure that IONSYS is not dispensed for use outside of the certified hospital.

IONSYS REMS Knowledge Assessment: This document tests healthcare providers’ knowledge of the appropriate assembly and use of IONSYS, including important risk messages associated with the safe use of IONSYS.

IONSYS REMS Website: This guide, other educational materials, letters, the IONSYS REMS Hospital Enrollment Form, and other important safety information are available on the IONSYS REMS Website (www.IONSYSREMS.com).
OTHER IONSYS MATERIALS (Available on www.IONSYSREMS.com website)

IONSYS Instructions for Use and Disposal (IFUD): This is a helpful guide that explains how to safely use and dispose of IONSYS. It also includes a section on how to troubleshoot any problems with IONSYS. This IFUD is included with each IONSYS and on the IONSYS REMS website.

IONSYS Medication Guide A quick reference guide for patients with patient-friendly text describing how to use IONSYS and important risk messages to review with patients to promote the safe use of IONSYS. This guide is included with each IONSYS and on the IONSYS REMS website.

Prescribing Information: This document provides the prescribing information for IONSYS (fentanyl iontophoretic transdermal system), which includes instructions for use and disposal. (It also includes the IONSYS Medication Guide as an attachment).

OPTIONS FOR EDUCATION AND TRAINING

Nurses and pharmacists may complete training and the IONSYS REMS Knowledge Assessment online by accessing the Healthcare Providers tab on the IONSYS REMS website (www.IONSYSREMS.com). Alternatively, the IONSYS REMS Knowledge Assessment may be downloaded, completed, and returned to the hospital Authorized Representative following a complete review of the training materials available on the website.

ADVERSE EVENT REPORTING

Healthcare providers should report all suspected adverse reactions associated with the use of IONSYS. Please contact The Medicines Company via the IONSYS REMS Program toll-free at 1-877-488-6835 or the FDA at 1-800-FDA-1088 or at http://www.fda.gov/medwatch.

CONTACT INFORMATION FOR THE IONSYS REMS PROGRAM

www.IONSYSREMS.com or toll free at 1-877-488-6835.

Attachment A: IONSYS Medication Guide

Attachment B: IONSYS Instructions for Use and Disposal