

Initial REMS approval: 04/2015

Most recent modification: 11/2015

NDA 21338 IONSYS® (fentanyl iontophoretic transdermal system)

Fentanyl/Opioid

The Medicines Company

8 Sylvan Way, Parsippany NJ 07054

Phone: 973-290-6050

## **RISK EVALUATION AND MITIGATION STRATEGY (REMS)**

### **I. GOAL**

The goal of the IONSYS REMS is to mitigate the risk of respiratory depression resulting from accidental exposure to persons for whom it is not prescribed by:

- Ensuring dispensing to patients in certified hospitals only; and
- Informing healthcare providers of the serious risk of respiratory depression resulting from accidental exposure.

### **II. REMS Elements**

#### **A. Elements to Assure Safe Use**

1. IONSYS is dispensed to patients only in hospitals that are specially certified.
  - a. To become specially certified to dispense IONSYS in the IONSYS REMS Program, each certified hospital must:
    - i. Designate an Authorized Representative to complete the enrollment process by submitting the completed IONSYS REMS Hospital Enrollment Form on behalf of the certified hospital.
    - ii. Ensure the Authorized Representative will oversee implementation and compliance with the IONSYS REMS Program requirements by the following:
      - 1) Review the IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists (to which the *IONSYS Instructions for Use and Disposal* and the *IONSYS Guide for Patients* are attached) and successfully complete the IONSYS REMS Knowledge Assessment.
      - 2) Ensure that all staff involved in the dispensing and administration of IONSYS are trained on the IONSYS REMS Program requirements as described in the Ionsys REMS Safety Brochure: Guide for Nurses and Pharmacists (to which the IONSYS Instructions for Use and Disposal

and the IONSYS Guide for Patients are attached) and successfully complete the Ionsys Knowledge Assessment, and understand the key risk messages for patients described in the IONSYS Guide for Patients.

- 3) Ensure that the certified hospital staff involved in the prescribing, dispensing, and administration of IONSYS are informed of risk of respiratory depression and the elements of the IONSYS REMS by distributing the Dear Healthcare Provider Letters and Dear Hospital Pharmacy Letter within 3 weeks of receiving notification from the Medicines Company of certification in the IONSYS REMS Program.
  - 4) Renew enrollment in the IONSYS REMS Program every 3 years from initial enrollment.
  - 5) Put processes and procedures in place to ensure that IONSYS is not dispensed for use outside of a certified hospital.
  - 6) Comply with requests to be audited by The Medicines Company, FDA, or a third party to ensure that all training, processes and procedures for the IONSYS REMS Program are in place and are being followed and appropriate documentation is available upon request.
- b. A certified hospital must re-certify in the IONSYS REMS Program within 4 weeks if the hospital designates a new Authorized Representative.
  - c. The Medicines Company will:
    - i. Ensure that IONSYS is dispensed only by hospitals that are specially certified.
    - ii. Ensure that certified hospital enrollment can be completed online, faxed, or mailed to the IONSYS REMS Program.
    - iii. Ensure that certified hospital are notified when they have been certified by the IONSYS REMS Program. Ensure that the Authorized Representative in certified hospitals are notified following certification in the IONSYS REMS program. This notification must include a certification notification letter, Dear Healthcare Provider Letters and Dear Hospital Pharmacy Letter which the Authorized Representative must distribute to fulfill certification requirements in the IONSYS REMS Program.
    - iv. Verify every year that the Authorized Representative is the current designated Authorized Representative for the certified hospitals. If different, the hospital will be required to re-certify with a new Authorized Representative.
2. IONSYS will be dispensed to patients only in certain healthcare settings, specifically certified hospitals.
    - a. The Medicines Company will ensure that IONSYS will be dispensed only in certified hospitals to ensure healthcare providers who prescribe and administer IONSYS are

informed about the serious risk of respiratory depression resulting from accidental exposure.

3. The following materials are part of the REMS and are appended:
  - a. IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists
  - b. IONSYS REMS Knowledge Assessment
  - c. IONSYS REMS Dear Healthcare Provider Letters
  - d. IONSYS REMS Dear Hospital Pharmacy Letter
  - e. IONSYS REMS Hospital Enrollment Form

### **III. Implementation System**

- a. The Medicines Company will ensure that IONSYS is only distributed to certified hospitals by:
  - i. Ensuring that wholesalers/distributors who distribute IONSYS comply with the program requirements for wholesalers/distributors. In order for a wholesaler/distributor to distribute IONSYS, the wholesaler/distributor must:
    - 1) Put processes and procedures in place to verify, prior to distributing IONSYS, that the hospitals are certified.
    - 2) Train all relevant staff on the IONSYS REMS Program requirements.
    - 3) Agree to be audited by The Medicines Company, FDA, or a third party to ensure that all processes and procedures are in place and are being followed for the IONSYS REMS Program and appropriate documentation is available upon request.
    - 4) Agree to maintain distribution records and provide distribution data to the The Medicines Company
  - ii. Ensuring that wholesalers/distributors maintain distribution records of all shipments of IONSYS and agree to provide the data to the The Medicines Company.
- b. The Medicines Company will monitor distribution data and audit the wholesalers/ distributors within 180 days after the wholesaler/distributor initiates participation in the REMS program to ensure that all processes and procedures are in place and functioning to support the requirements of the IONSYS REMS Program. Corrective action will be instituted by The Medicines Company if noncompliance is identified. Corrective action may include de-certifying non-compliant hospitals.
- c. The Medicines Company will maintain a validated, secure database of hospitals who are certified to dispense IONSYS in the IONSYS REMS Program.

- d. The Medicines Company will ensure that the certified hospitals REMS requirements are met and may de-certify non-compliant hospitals if the requirements do not continue to be met.
- e. The Medicines Company will maintain records of IONSYS distribution to certified hospitals, certified hospitals, and wholesalers/distributors to meet REMS requirements.
- f. The Medicines Company will ensure all materials listed in or appended to the IONSYS REMS are available through the IONSYS REMS Program website ([www.IONSYSREMS.COM](http://www.IONSYSREMS.COM)) or through the IONSYS REMS Program Call Center. The REMS program website will include the option to print the Full Prescribing Information and IONSYS REMS materials, including the Knowledge Assessment. The IONSYS product website will include a prominent REMS-specific link to IONSYS REMS Program website ([www.IONSYSREMS.com](http://www.IONSYSREMS.com)).
- g. The Medicines Company will monitor and audit the certified hospitals within 180 days after the hospitals places its first order of IONSYS to ensure that all processes and procedures are in place and functioning to support the requirements of the IONSYS REMS Program. These certified hospitals will also be included in The Medicines Company's ongoing monitoring and annual audit plan. Corrective action will be instituted by The Medicines Company if noncompliance is identified. Corrective action may include de-certifying non-compliant hospitals.
- h. The Medicines Company will take reasonable steps to improve implementation of and compliance with the requirements in the IONSYS REMS Program based on monitoring and evaluation of the IONSYS REMS Program.

#### **IV. Timetable for Submission of Assessments**

The Medicines Company will submit REMS assessments to the FDA at 6 months and 12 months from the approval date of the initial REMS and annually thereafter. 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 days before the submission date for that assessment. The Medicines Company will submit each assessment so that it will be received by the FDA on or before the due date.

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 in adult patients requiring opioid analgesia **in the hospital**. 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 Guide for Patients* (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](http://www.IONSYSREMS.com) website)

**Dear Healthcare Provider Letters:** Intended for Hospital Heads of Pharmacy, Nursing, General Surgery, Anesthesia, Obstetrics and Gynecology, and Orthopedics at certified hospitals.

**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](http://www.IONSYSREMS.com)).

**OTHER IONSYS MATERIALS** (Available on [www.IONSYSREMS.com](http://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 trouble shoot any problems with IONSYS. This IFUD is included with each IONSYS and on the IONSYS REMS website.

**IONSYS Guide for Patients:** 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.

**Full Prescribing Information:** This document provides the full prescribing information for IONSYS (fentanyl iontophoretic transdermal system), which includes instructions for use and disposal. (It also includes the *IONSYS Guide for Patients* 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](http://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](http://www.IONSYSREMS.com) or toll free at 1-877-488-6835.

Attachment A:

Attachment B:

*IONSYS Guide for Patients*

*IONSYS Instructions for Use and Disposal*

The nine questions below will test your knowledge of the appropriate use of IONSYS® (fentanyl iontophoretic transdermal system), including important risk messages associated with its safe use. Please review the following materials before taking this Knowledge Assessment:

- **IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists**
- **IONSYS Instructions for Use and Disposal**
- **IONSYS Guide for Patients**
- **IONSYS Full Prescribing Information**

After answering all questions, please fill in your details and do the following:

- If you are the Hospital Authorized Representative, please fax the completed pages to 1-877-488-8601. You may also complete and submit this online at [www.IONSYSREMS.com](http://www.IONSYSREMS.com) via the **Hospital Certification** tab.
- If you are a Nurse or Pharmacist, please provide your completed assessment to your Authorized Representative. You may also complete and submit this online at [www.IONSYSREMS.com](http://www.IONSYSREMS.com) via the **Healthcare Providers** tab.

| Hospital Authorized Representative, Nurse, or Pharmacist       |                                |   |
|--|--------------------------------|---|
| Name (first, middle, and last):                                |                                |   |
| Affiliation with Hospital (please check one):                  |                                |   |
| <input type="checkbox"/> Hospital Authorized Representative    | <input type="checkbox"/> Nurse | <input type="checkbox"/> Pharmacist <input type="checkbox"/> Other: _____ |
| Name of Hospital:  |                                |   |
| Hospital Pharmacy Street Address:                              |                                |   |
| City:  | State:                         | Zip Code:   |
| DEA License Number (Authorized Representative only):           |                                |   |
| State License Number (Optional for Authorized Representative): | License State:                 |   |

**Question 1**

The IONSYS Risk Evaluation and Mitigation Strategy (REMS) is required by the Food and Drug Administration (FDA) to: Select one option.

- A. Prevent respiratory depression resulting from accidental exposure to persons for whom it is not prescribed
- B. Educate healthcare providers about the risk of respiratory depression associated with IONSYS
- C. Ensure that IONSYS is dispensed and administered only within hospitals
- D. All of the above

**Question 2**

It is important that only healthcare providers are educated about the safe use of IONSYS. Select one option.

- A. True
- B. False

**Question 3**

IONSYS may be sent home with the patient upon leaving from the hospital. *Select one option.*

- A. True
- B. False

**Question 4**

Healthcare providers (nurses and pharmacists) should avoid contact with the IONSYS hydrogel (i.e., wear gloves) when:

*Select one option.*

- A. Applying IONSYS
- B. Monitoring Patient Use of IONSYS
- C. Removing IONSYS
- D. Disposing of IONSYS
- E. All of the above

**Question 5**

The **IONSYS Guide for Patients** contains important information for the patient. Which one of the following statements is accurate?

*Select one option.*

- A. The IONSYS REMS Program will provide this guide to patients by mail after a patient has left the hospital.
- B. This guide only needs to be reviewed with the patient's caregiver before initiating treatment with IONSYS, because the patient may not be able to understand the instructions for use
- C. This guide should be reviewed with patients and caregivers before initiating treatment with IONSYS
- D. The **IONSYS Guide for Patients** can only be obtained from hospital pharmacies

**Question 6**

There is a risk of fatal overdose with inappropriate use or handling of IONSYS. Which of the following answers is most accurate?

*Select one option.*

- A. IONSYS can be fatal if misused by children
- B. IONSYS can be fatal if used by anyone for whom it is not prescribed
- C. IONSYS can be fatal if the hydrogels are ingested or if they come into contact with a healthcare provider's or patient's mucous membranes
- D. All of the above

**Question 7**

Which of the following statements is accurate regarding safe disposal of IONSYS? *Select one option.*

- A. IONSYS units should be removed using gloves - assuring both hydrogels remain with the unit
- B. The bottom housing containing the gels should be separated from the electronics (top housing) by pulling the red tab, and the bottom should be folded in half with the sticky side facing in. It should be disposed by flushing down the toilet or following institutional procedures
- C. Disposal of IONSYS should comply with hospital operating policies and procedures
- D. All of the above

**Question 8**

Which of the following factors increases the risk of overdose of fentanyl from IONSYS? *Select one option.*

- A. Instructing someone other than the patient to administer doses from IONSYS
- B. The patient must press the dose button twice within 3 seconds to administer a dose from IONSYS
- C. Applying only one IONSYS to a patient at any time
- D. IONSYS should only be applied to patients who can understand how to use IONSYS without help

**Question 9**

What action is most likely to prevent IONSYS from being used outside of the hospital? *Select one option.*

- A. Having inadequate record keeping of IONSYS dispensing
- B. Removing IONSYS from the patient prior to leaving the hospital
- C. Having inadequate hospital procedures for IONSYS disposal
- D. Applying IONSYS to the upper, outer arm, or chest

**Subject: Risk of respiratory depression resulting from accidental exposure to IONSYS® (fentanyl iontophoretic transdermal system);**  
FDA-required Risk Evaluation and Mitigation Strategy (REMS)

**Dear Department Head, Nursing:**

The purpose of this letter is to inform you of important safety information for IONSYS, a patient-controlled iontophoretic transdermal system providing patient controlled analgesia of fentanyl, an opioid agonist.

IONSYS has been approved by the US Food and Drug Administration (FDA) for the short term management of acute postoperative pain in adult patients requiring opioid analgesia while in the hospital. IONSYS contains fentanyl, a Schedule II controlled substance (CII) with abuse similar to other opioid analgesics. Patients should be titrated to an acceptable level of analgesia before initiating treatment with IONSYS.

The FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary to ensure that the benefits of IONSYS outweigh the risk of respiratory depression resulting from accidental exposure. **Recently, your hospital became certified in the IONSYS REMS Program.**

**SAFE USE OF IONSYS**

- Hospitals must be certified in the IONSYS REMS Program to order, dispense, and administer IONSYS
- Nurses and pharmacists must review key risk messages for healthcare providers using the healthcare provider education and training listed below
- IONSYS should only be used by patients in a hospital setting, must be discontinued prior to 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 Guide for Patients*
- Healthcare providers should avoid contact with the hydrogel

**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 setup and appropriate use of IONSYS. Tools for healthcare provider training and patient education include:

1. **IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists:** A guide for nurses and pharmacists who dispense, set up, and/or administer IONSYS. It includes clear information about the important risk messages associated with the IONSYS REMS Program required by the FDA. (It also includes the *IONSYS Instructions for Use and Disposal* and the *IONSYS Guide for Patients* as attachments). A copy of the safety brochure is enclosed with this letter.
2. **IONSYS REMS Knowledge Assessment:** This document tests healthcare providers' knowledge of the appropriate set up and use of IONSYS, including important risk messages associated with the safe use of IONSYS. A copy is enclosed with this letter.
3. **Full Prescribing Information:** This document provides the full prescribing information for IONSYS (fentanyl iontophoretic transdermal system), which includes instructions for use and disposal. (It also includes the *IONSYS Guide for Patients* as an attachment).
4. **Dear Healthcare Provider Letters:** Intended for certified hospital Heads of Pharmacy, Nursing, General Surgery, Anesthesia, Obstetrics and Gynecology, and Orthopedics.

5. **IONSYS REMS Hospital Enrollment Form:** IONSYS can only be ordered, dispensed, and administered in hospitals which have been certified in the IONSYS REMS Program. The hospital Authorized Representative ensures that the institution has documented processes in place to ensure compliance with the requirements of the IONSYS REMS including the requirement that IONSYS is not dispensed for use outside of the certified hospital.
6. **IONSYS REMS Website:** Tools for healthcare provider training and patient education, letters, the **IONSYS REMS Hospital Enrollment Form**, and other important safety information are available on the IONSYS REMS Website ([www.IONSYSREMS.com](http://www.IONSYSREMS.com)). Nurses and pharmacists may complete training and the **IONSYS REMS Knowledge Assessment** by accessing the *Healthcare Providers* tab on the IONSYS REMS website ([www.IONSYSREMS.com](http://www.IONSYSREMS.com)).

#### HOSPITAL CERTIFICATION

Hospitals must certify in the IONSYS REMS Program. To become certified, an Authorized Representative of the hospital (e.g., Pharmacy and Therapeutics Chair, Pharmacy Director, Medical Chief of Staff, or Head of Nursing Staff) must review the IONSYS REMS tools for healthcare provider training and patient education, successfully complete the **IONSYS REMS Knowledge Assessment**, and submit the **IONSYS REMS Hospital Enrollment Form**. In order to complete certification, the Authorized Representative must train staff and develop processes, procedures, and/or other measures (e.g., order sets) to ensure IONSYS is not dispensed for use outside of the certified hospital.

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](http://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 IONSYS REMS website.

Healthcare providers and patients are encouraged to **report adverse events** in patients taking IONSYS to The Medicines Company via the IONSYS REMS Program at 1-877-488-6835 or the FDA at 1-800-FDA-1088 (1-800-332-1088), or visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

This letter is not a comprehensive description of the risks associated with the use of IONSYS. Refer to the full Prescribing Information for a complete description of these risks.

If you have questions about the IONSYS REMS Program or how hospitals are certified in the IONSYS REMS Program, please visit [www.IONSYSREMS.com](http://www.IONSYSREMS.com) for more information or call the toll-free number: 1-877-488-6835.

Sincerely,

The Medicines Company  
Enclosures:

**Full Prescribing Information**  
**IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists**  
**IONSYS REMS Knowledge Assessment**

**Subject: Risk of respiratory depression resulting from accidental exposure to IONSYS® (fentanyl iontophoretic transdermal system);**  
FDA-required Risk Evaluation and Mitigation Strategy (REMS)

**Dear Director of Hospital Pharmacy:**

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6. **IONSYS REMS Website:** Tools for healthcare provider training and patient education, letters, the **IONSYS REMS Hospital Enrollment Form**, and other important safety information are available on the IONSYS REMS Website ([www.IONSYSREMS.com](http://www.IONSYSREMS.com)). Pharmacists and nurses may complete training and the **IONSYS REMS Knowledge Assessment** by accessing the **Healthcare Providers** tab on the IONSYS REMS website ([www.IONSYSREMS.com](http://www.IONSYSREMS.com)).

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#### ROLE OF THE DEPARTMENT OF PHARMACY

The Department of Pharmacy plays an important role in the enrollment and certification of the hospital, as they may be asked to take the lead in:

- **certifying** their hospital in the IONSYS REMS Program,
- **developing** processes, procedures, and/or other measures to ensure IONSYS is not dispensed for outpatient use or to a patient leaving the hospital,
- **training** hospital staff in the safe use of IONSYS which includes informing health care providers of the serious risk of respiratory depression resulting from accidental exposure and the need to counsel patients on the aforementioned risks,
- **servicing** as a resource when IONSYS is implemented hospital-wide.

Healthcare providers and patients are encouraged to **report adverse events** in patients taking IONSYS to The Medicines Company via the IONSYS REMS Program at 1-877-488-6835 or the FDA at 1-800-FDA-1088 (1-800-332-1088), or visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

This letter is not a comprehensive description of the risks associated with the use of IONSYS. Refer to the full Prescribing Information for a complete description of these risks.

**IONSYS®**  
(fentanyl iontophoretic  
transdermal system)©

**IMPORTANT DRUG WARNING**

If you have questions about the IONSYS REMS Program or how hospitals are certified in the IONSYS REMS Program, please visit [www.IONSYSREMS.com](http://www.IONSYSREMS.com) for more information or call the toll-free number: 1-877-488-6835.

Sincerely,

The Medicines Company

Enclosures:

**Full Prescribing Information**

**IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists**

**IONSYS REMS Knowledge Assessment**

**The  
Medicines  
Company**

If you have any questions regarding IONSYS or the IONSYS REMS Program call 877-488-6835

Page 3 of 3

Version 2.0 - September 29, 2015

IONSYS® (fentanyl iontophoretic transdermal system) is only available through the IONSYS Risk Evaluation and Mitigation Strategy (REMS) developed by The Medicines Company. Under the IONSYS REMS Program, IONSYS can only be ordered, prescribed, dispensed, and administered in hospitals that are certified in the REMS Program.

To initiate certification for your hospital, an Authorized Representative must confirm his or her understanding of the IONSYS REMS Program requirements by reviewing the tools for healthcare provider training and patient education and completing, signing, and submitting the **IONSYS REMS Hospital Enrollment Form** and the **IONSYS REMS Knowledge Assessment**. Submission may be completed online at [www.IONSYSREMS.com](http://www.IONSYSREMS.com), by fax to 1-877-488-8601, or by mailing the forms to the IONSYS REMS Program to P.O. Box 29242, Phoenix, AZ 85038-9242. Once the IONSYS REMS Program processes the **IONSYS REMS Hospital Enrollment Form**, a hospital certification notification letter and the IONSYS REMS materials will be provided to the Authorized Representative. The Authorized Representative must follow IONSYS REMS requirements and utilize the educational tools to train hospital staff involved in the prescribing, dispensing, and administration of IONSYS. Following certification, the hospital may order, prescribe, dispense, and administer IONSYS.

I understand that IONSYS is only available through the IONSYS REMS Program. As the designated Authorized Representative, I must comply with the following program requirements for hospitals to ensure that IONSYS is only ordered, prescribed, dispensed, and administered in certified hospitals. I acknowledge that:

1. I am the Authorized Representative designated by my hospital to complete certification on behalf of the hospital and oversee implementation and compliance with the IONSYS REMS Program.
2. I attest that this hospital provides acute care, treats patients in the hospital, and offers post-operative pain management.
3. I have reviewed the IONSYS Prescribing Information, **IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists** (to which the **IONSYS Instructions for Use and Disposal** and the **IONSYS Guide for Patients** are attached), and I have successfully completed the **IONSYS REMS Knowledge Assessment**.
4. I understand the benefits and risks associated with IONSYS and the requirements of the IONSYS REMS Program.
5. I will ensure all staff, including pharmacy and nursing staff, involved in dispensing or administering IONSYS have been trained on the IONSYS REMS Program requirements as described in the **IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists** (to which the **IONSYS Instructions for Use and Disposal** and the **IONSYS Guide for Patients** are attached) and have successfully completed the **IONSYS REMS Knowledge Assessment**. This training will be documented.
6. I will establish or oversee the processes, procedures, systems, order sets, protocols, and/or other measures to help ensure compliance with the requirements of the IONSYS REMS Program. These processes, procedures, and/or other measures will be documented.
7. I understand that the hospital will not sell, loan, or transfer IONSYS inventory to any other pharmacy, institution, distributor, or prescriber.
8. I will ensure that the certified hospital staff involved in the prescribing, dispensing, and administration of IONSYS are informed of risk of respiratory depression and the elements of the IONSYS REMS by distributing the Dear Healthcare Provider Letters and Dear Hospital Pharmacy Letter within 3 weeks of receiving notification of certification in the IONSYS REMS Program.
9. I understand that the hospital pharmacy is not to dispense IONSYS for use outside the hospital.
10. I understand that IONSYS must be removed from the patient prior to the patient leaving the hospital.
11. I will report any adverse events suggestive of respiratory depression resulting from accidental exposure associated with the use of IONSYS to The Medicines Company or the FDA.
12. I will comply with requests to be audited by The Medicines Company to ensure that all processes and procedures are in place and are being followed for the IONSYS REMS Program and appropriate documentation is available upon request.
13. I will renew this hospital's certification in the IONSYS REMS Program every 3 years after initial certification.
14. I understand this hospital must have a new Authorized Representative complete an **IONSYS REMS Hospital Enrollment Form** and successfully complete the **IONSYS REMS Knowledge Assessment** within 4 weeks of the hospital designating a new Authorized Representative.

All Fields Required Unless Otherwise Indicated.

|  |             |                |
|--|-------------|----------------|
| <b>Authorized Representative Signature:</b>  |             | <b>Date:</b>   |
| Authorized Representative Printed Name (First, Last):  |             | Title:         |
| If State License Number is provided, License State and State License Type fields are required.   |             |                |
| Authorized Representative State License Number (optional):   |             | License State: |
| State License Type: <input type="checkbox"/> MD <input type="checkbox"/> DO <input type="checkbox"/> PA <input type="checkbox"/> RN <input type="checkbox"/> NP <input type="checkbox"/> RPh <input type="checkbox"/> PharmD <input type="checkbox"/> Other: _____ |             |                |
| Name of Hospital:  |             |                |
| Hospital Pharmacy Street Address:  |             |                |
| City:  | State:      | Zip Code:      |
| State Hospital License Number:   |             | License State: |
| Phone Number:  | Fax Number: |                |
| Email Address:   |             |                |
| Preferred Method of Communication (Please choose one): <input type="checkbox"/> Email <input type="checkbox"/> Fax   |             |                |
| Hospital Pharmacy DEA License Number:  |             |                |
| Hospital Pharmacy DEA License Number Expiration Date (optional):   |             |                |

If you have any questions, require additional information, or need further copies of all IONSYS REMS materials, please visit [www.IONSYSREMS.com](http://www.IONSYSREMS.com), or contact the IONSYS REMS Program at 1-877-488-6835.

The Medicines Company

This form is part of an FDA-approved REMS.

For more information about IONSYS, please see Full Prescribing Information, including Boxed Warnings.

# **IONSYS REMS Program**

## **Risk Evaluation and Mitigation Strategy**

**Website Mockups**

**V6**

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## 1. Footer

*Footer is included on every web page. To reduce the length of the document, the screenshot is included once.*



For additional information about the IONSYS REMS Program, please call 877-488-6835.

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## 2. Home Page

**IONSYS®**  
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### IONSYS® Risk Evaluation and Mitigation Strategy (REMS) Program

A REMS is a strategy to manage known or potential serious risks associated with a drug product and is required by the Food and Drug Administration (FDA) to ensure the benefits of a drug outweigh its risks. **The goal of the IONSYS REMS is to mitigate the risks of respiratory depression resulting from accidental exposure to persons for whom it is not prescribed.** The Medicines Company has worked with the FDA to develop the IONSYS REMS Program to mitigate this potential risk.



**Get Started Now!**

Certify your hospital in  
the IONSYS REMS Program.

[Start Certification](#)

#### Safe Use of IONSYS

- 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 Guide for Patients* (included with each IONSYS)
  - 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

#### What is IONSYS?

IONSYS is an opioid analgesic that should only be used for the short-term management of acute postoperative pain in adult patients requiring opioid analgesia in the **hospital**. 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.

#### Resources for Healthcare Providers

[IONSYS REMS Hospital Enrollment Form](#)

[IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists](#)

[IONSYS REMS Knowledge Assessment](#)

[Dear Healthcare Provider Letter - Department Head: Surgery](#)

[Dear Healthcare Provider Letter - Department Head: Anesthesia](#)

[Dear Healthcare Provider Letter - Department Head: Nursing](#)

[Dear Healthcare Provider Letter - Department Head: Obstetrics and Gynecology](#)

[Dear Healthcare Provider Letter - Department Head: Orthopedics](#)

[Dear Hospital Pharmacy Letter](#)

[IONSYS Instructions for Use and Disposal](#)

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#### Resources for Patients

[IONSYS Guide for Patients](#)

### 3. Home Page – Signed-In

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## IONSYS® Risk Evaluation and Mitigation Strategy (REMS) Program

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- [IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists](#)
- [IONSYS REMS Knowledge Assessment](#)
- [Dear Healthcare Provider Letter - Department Head: Surgery](#)
- [Dear Healthcare Provider Letter - Department Head: Anesthesia](#)
- [Dear Healthcare Provider Letter - Department Head: Nursing](#)
- [Dear Healthcare Provider Letter - Department Head: Obstetrics and Gynecology](#)
- [Dear Healthcare Provider Letter - Department Head: Orthopedics](#)
- [Dear Hospital Pharmacy Letter](#)
- [IONSYS Instructions for Use and Disposal](#)
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#### Resources for Patients

- [IONSYS Guide for Patients](#)

## 4. Patient Information 1<sup>st</sup> Section

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### IONSYS Guide for Patients

#### • Important

- IONSYS is only for use in the hospital. Do not leave the hospital with an IONSYS on your skin
- IONSYS can cause life-threatening breathing problems or death if it is used other than described in the section "How do I use IONSYS?" below
- Keep the IONSYS out of the reach of children



#### • IONSYS

#### • Do not use IONSYS if you are allergic to

#### • Your healthcare provider

#### • How do I use IONSYS?

#### • Tell your healthcare provider right away if

#### • Do not

## 5. Patient Information 2<sup>nd</sup> Section

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### IONSYS Guide for Patients

#### ▶ Important

#### ▶ IONSYS

- Contains the prescription medicine, fentanyl. Fentanyl is a very strong narcotic pain medicine (opioid)
- Is only used in the hospital for adults with short-term pain after surgery
- Is a patient-controlled medicine system that sticks to the skin. It will be applied by your healthcare provider on your upper outer arm or chest

#### ▶ Do not use IONSYS if you are allergic to

#### ▶ Your healthcare provider

#### ▶ How do I use IONSYS?

#### ▶ Tell your healthcare provider right away if

#### ▶ Do not

## 6. Patient Information 3<sup>rd</sup> Section

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### IONSYS Guide for Patients

▶ **Important**

▶ **IONSYS**

▶ **Do not use IONSYS if you are allergic to**

- Fentanyl
- Cepacol (cetylpyridinium chloride)

▶ **Your healthcare provider**

▶ **How do I use IONSYS?**

▶ **Tell your healthcare provider right away if**

▶ **Do not**

## 7. Patient Information 4<sup>th</sup> Section

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### IONSYS Guide for Patients

#### • Important

#### • IONSYS

#### • Do not use IONSYS if you are allergic to

#### • Your healthcare provider

- Will tell you about IONSYS and teach you how to use it
- Will put IONSYS on your skin (on your upper outer arm or chest) after your surgery
- Will control pain from your surgery with other pain medicines until you are awake enough to use IONSYS
- Will check you for side effects from IONSYS
- Must replace your IONSYS as needed. You should not replace your IONSYS yourself
- Will remove your IONSYS before you leave the hospital. **Do not leave the hospital with an IONSYS on your skin**

#### • How do I use IONSYS?

#### • Tell your healthcare provider right away if

#### • Do not

## 8. Patient Information 5<sup>th</sup> Section

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### IONSYS Guide for Patients

#### ▶ Important

#### ▶ IONSYS

#### ▶ Do not use IONSYS if you are allergic to

#### ▶ Your healthcare provider

#### ▶ How do I use IONSYS?

- You can push the IONSYS dosing button when you need to control your pain or just before you do an activity that may increase your pain - such as physical therapy or getting out of bed
- To get a dose of pain medicine from IONSYS, **press and release the dosing button twice within 3 seconds**
- When you push the dosing button you will hear a single beep and the green light will start blinking quickly. The green light will continue to blink quickly for the 10 minutes it takes to deliver a dose of IONSYS
- During this time, IONSYS will not deliver another dose even if you press the dosing button again
- IONSYS can only be activated every 10 minutes
- When IONSYS is finished delivering a dose, the green light will start blinking slowly. This means you can give yourself more pain medicine, if needed. Just press and release the dosing button twice within 3 seconds like you did before. The digital display will tell your healthcare provider how many doses you have received. Each IONSYS may be used for up to 24 hours or a maximum of 80 doses, whichever comes first
- If IONSYS starts beeping at any time tell your healthcare provider right away



#### ▶ Tell your healthcare provider right away if

#### ▶ Do not

## 9. Patient Information 6<sup>th</sup> Section

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### IONSYS Guide for Patients

▶ **Important**

▶ **IONSYS**

▶ **Do not use IONSYS if you are allergic to**

▶ **Your healthcare provider**

▶ **How do I use IONSYS?**

▶ **Tell your healthcare provider right away if**

- You have any questions about IONSYS
- You are still having pain
- IONSYS falls off your skin
- You have trouble using IONSYS. Your healthcare provider will check your IONSYS to make sure it is working

▶ **Do not**

## 10. Patient Information 7<sup>th</sup> Section

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### IONSYS Guide for Patients

▶ Important

▶ IONSYS

▶ Do not use IONSYS if you are allergic to

▶ Your healthcare provider

▶ How do I use IONSYS?

▶ Tell your healthcare provider right away if

▼ Do not

- Do not let anyone else press the IONSYS dosing button for you. **You are the only person who should push the dosing button**
- Do not touch IONSYS if it falls off of your skin. Tell your healthcare provider right away if your IONSYS comes off of your skin. Rinse your hands with water (do not use soap) right away if you accidentally touch the sticky side of IONSYS, and tell your healthcare provider right away
- Do not let others touch IONSYS
- Do not remove or replace IONSYS yourself
- Do not leave the hospital with an IONSYS on your skin. **Make sure your healthcare provider removes your IONSYS before you leave the hospital**

# 11. Hospital Certification



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- Healthcare Providers
- Forms & Resources

## Hospital Certification

### Steps for Hospital Certification

All hospitals must be certified in the IONSYS REMS Program in order to dispense and administer IONSYS. Certification requires the identification of an Authorized Representative for the hospital to complete the certification process.

- Hospitals will be notified that they have been certified in the IONSYS REMS Program.
- Hospitals must put processes and procedures in place to ensure that IONSYS is not dispensed for use outside of a certified hospital.
- The Medicines Company will verify every year that the Authorized Representative is the current designated Authorized Representative.

Certification in the IONSYS REMS Program includes the following steps:

| Designate   | Educate  | Assess   | Attest  | Distribute   | Train  | Maintain   |
|---|--|--|---|--|--|--|
| Designate an Authorized Representative for the hospital | Review the IONSYS REMS Program education resources | Successfully complete the IONSYS REMS Knowledge Assessment | Complete and sign the IONSYS REMS Hospital Enrollment Form. The certification must be renewed every three (3) years | Distribute Dear Healthcare Provider Letters along with IONSYS REMS Program education materials to the following hospital department heads: Surgery, Anesthesia, Nursing, Obstetrics/ Gynecology, Orthopedics, and Pharmacy | Train all staff who dispense or administer IONSYS (nurses and pharmacists) and ensure they complete the IONSYS REMS Knowledge Assessment | Maintain the list of the healthcare providers trained in the IONSYS REMS Program |

If you have been designated as your hospital's Authorized Representative, please use the **Start Certification** button to start your certification today. You can also download the print version of the education resources and fax or mail your **IONSYS REMS Hospital Enrollment Form** and **IONSYS REMS Knowledge Assessment** to the IONSYS REMS Program at fax number 877-488-8601 or mail to IONSYS REMS Program P.O. Box 29242, Phoenix, AZ 85038-9242.

[Start Certification](#)

### Education Resources

- [IONSYS REMS Hospital Enrollment Form](#)
- [IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists](#)
- [IONSYS REMS Knowledge Assessment](#)
- [Dear Healthcare Provider Letter – Department Head: Surgery](#)
- [Dear Healthcare Provider Letter – Department Head: Anesthesia](#)
- [Dear Healthcare Provider Letter – Department Head: Nursing](#)
- [Dear Healthcare Provider Letter – Department Head: Obstetrics and Gynecology](#)
- [Dear Healthcare Provider Letter – Department Head: Orthopedics](#)
- [Dear Hospital Pharmacy Letter](#)
- [IONSYS Instructions for Use and Disposal](#)
- [IONSYS Guide for Patients](#)
- [Full Prescribing Information](#)

## 12. Hospital Certification – Signed-In

### Hospital Certification

#### Steps for Hospital Certification

All hospitals must be certified in the IONSYS REMS Program in order to dispense and administer IONSYS. Certification requires the identification of an Authorized Representative for the hospital to complete the certification process.

- Hospitals will be notified that they have been certified in the IONSYS REMS Program.
- Hospitals must put processes and procedures in place to ensure that IONSYS is not dispensed for use outside of a certified hospital.
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|---|--|---|---|--|---|--|
| Designate an Authorized Representative for the hospital | Review the IONSYS REMS Program education resources | Successfully complete the <b>IONSYS REMS Knowledge Assessment</b> | Complete and sign the <b>IONSYS REMS Hospital Enrollment Form</b> . The certification must be renewed every three (3) years | Distribute Dear Healthcare Provider Letters along with IONSYS REMS Program education materials to the following hospital department heads: Surgery, Anesthesia, Nursing, Obstetrics/ Gynecology, Orthopedics, and Pharmacy | Train all staff who dispense or administer IONSYS (nurses and pharmacists) and ensure they complete the <b>IONSYS REMS Knowledge Assessment</b> | Maintain the list of the healthcare providers trained in the IONSYS REMS Program |

#### Education Resources

- [IONSYS REMS Hospital Enrollment Form](#)
- [IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists](#)
- [IONSYS REMS Knowledge Assessment](#)
- [Dear Healthcare Provider Letter – Department Head: Surgery](#)
- [Dear Healthcare Provider Letter – Department Head: Anesthesia](#)
- [Dear Healthcare Provider Letter – Department Head: Nursing](#)
- [Dear Healthcare Provider Letter – Department Head: Obstetrics and Gynecology](#)
- [Dear Healthcare Provider Letter – Department Head: Orthopedics](#)
- [Dear Hospital Pharmacy Letter](#)
- [IONSYS Instructions for Use and Disposal](#)
- [IONSYS Guide for Patients](#)
- [Full Prescribing Information](#)

### 13. Nurses and Pharmacists – Not Signed-In

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|------|---------------------|------------------------|----------------------|-------------------|

#### 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.

To complete the education and take the **IONSYS REMS Knowledge Assessment**, the following steps should be followed:

| Educate  | Assess   | Maintain  |
|--|--|---|
| Review the following IONSYS REMS Program education resources<br><a href="#">IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists</a><br><a href="#">IONSYS Instructions for Use and Disposal</a><br><a href="#">IONSYS Guide for Patients</a><br><a href="#">Full Prescribing Information</a> | Successfully complete the <a href="#">IONSYS REMS Knowledge Assessment</a> | Provide the Knowledge Assessment confirmation code (if completed online) or the completed Knowledge Assessment (if completed on paper) to the Authorized Representative of your hospital for the training record. |

Hospitals can choose whether nurses or pharmacists complete training online or on paper.

Please use the **Start** button to create an account, complete the education, and submit the **IONSYS REMS Knowledge Assessment** online. Once you have successfully completed your Knowledge Assessment, please provide the completed Knowledge Assessment confirmation code to your Authorized Representative of your Hospital for the training record.

[Start](#)

## 14. Nurses and Pharmacists – Signed-In

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### 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.

To complete the education and take the **IONSYS REMS Knowledge Assessment**, the following steps should be followed:

| Educate  | Assess   | Maintain  |
|--|--|---|
| Review the following IONSYS REMS Program education resources<br><a href="#">IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists</a><br><a href="#">IONSYS Instructions for Use and Disposal</a><br><a href="#">IONSYS Guide for Patients</a><br><a href="#">Full Prescribing Information</a> | Successfully complete the <a href="#">IONSYS REMS Knowledge Assessment</a> | Provide the Knowledge Assessment confirmation code (if completed online) or the completed Knowledge Assessment (if completed on paper) to the Authorized Representative of your hospital for the training record. |

## 15. Create an Account

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### Create an Account

To create your web account for the IONSYS REMS Program, please complete the fields below. The Username you specify must be unique within the IONSYS REMS Program website. All fields below are required unless otherwise indicated.

|                  |  |
|------------------|--|
| First Name       | <input type="text"/>   |
| Last Name        | <input type="text"/>   |
| Email Address    | <input type="text"/>   |
| Certification ID | <input type="text" value="Optional"/> ⓘ<br><small>(If you certified via fax, please enter your Certification ID)</small>   |
| Username         | <input type="text"/><br><a href="#">+ Suggest Username</a> <a href="#">🔍 Check Username Availability</a><br><input type="checkbox"/> Use Email Address as Username |
| Password         | <input type="password"/> ⓘ   |
| Confirm Password | <input type="password"/>   |

## 16. Stakeholder Identification Page

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### Stakeholder Identification

Please select one of the following stakeholder types to ensure you are directed to the process that is appropriate to your role:

- Hospital Authorized Representative** – The designated individual responsible for certifying their Hospital in the IONSYS REMS Program. This individual is responsible to attest to the program requirements and to oversee implementation and compliance with the IONSYS REMS Program. Hospital Authorized Representatives must be trained on the IONSYS REMS Program requirements and complete the *IONSYS REMS Program Knowledge Assessment* prior to attesting to the program requirements.
- Nurses and Pharmacists** – Pharmacy and Nursing staff involved in dispensing or administering IONSYS must be trained on the IONSYS REMS Program requirements as described in the *IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists* (to which the *IONSYS Instructions for Use and Disposal* and the *IONSYS Guide for Patients* are attached) and must complete and submit the *IONSYS REMS Program Knowledge Assessment* to the Authorized Representative of their hospital prior to dispensing or administering IONSYS for patient use.

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## 17. Hospital Intake

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### Hospital Intake

To certify your hospital in the IONSYS REMS Program, please complete the form below and submit. Once certified, you will receive a certification confirmation via your preferred method of communication. All fields below are required unless otherwise indicated.

#### Authorized Representative Intake

First Name

Last Name

Title

State License Number  Optional State

State License Type  Other

Phone  Ext  Optional

Fax

Email Address

Preferred Method of Communication  Email  Fax

#### Hospital Intake

Hospital Name

Hospital Address

Hospital Address 2  Optional

Hospital City

Hospital State  Hospital Zip

State Hospital License Number  State

Hospital DEA Number

DEA License Expiration  Optional

Cancel

Submit

## 18. Nurses and Pharmacists Intake

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### Nurses and Pharmacists Intake

Please complete the form below and submit. Once you have completed the Knowledge Assessment, you will receive a confirmation via your contact preference. All fields below are required unless otherwise indicated.

|                                   |                             |                           |                      |
|-----------------------------------|-----------------------------|---------------------------|----------------------|
| First Name                        | <input type="text"/>        |                           |                      |
| Last Name                         | <input type="text"/>        |                           |                      |
| State License Number              | <input type="text"/>        | State                     | <input type="text"/> |
| State License Type                | <input type="text"/>        |                           |                      |
| Phone                             | <input type="text"/>        | Ext                       | <input type="text"/> |
| Fax                               | <input type="text"/>        |                           |                      |
| Email Address                     | <input type="text"/>        |                           |                      |
| Preferred Method of Communication | <input type="radio"/> Email | <input type="radio"/> Fax |                      |

## 19. Hospital Lookup for Nurses and Pharmacists

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### Hospital Lookup for Nurses and Pharmacists

Please use the search function below to find the hospital in which you are affiliated. Linking to your affiliated hospital will allow your Authorized Representative to track the completion of your training and Knowledge Assessment.

|                                  |        |                              |         |                               |        |
|----------------------------------|--------|------------------------------|---------|-------------------------------|--------|
| Zip Code<br><input type="text"/> | - or - | City<br><input type="text"/> | - and - | State<br><input type="text"/> | Search |
|----------------------------------|--------|------------------------------|---------|-------------------------------|--------|

## 20. Hospital Lookup for Nurses and Pharmacists with Search Result

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### Hospital Lookup for Nurses and Pharmacists

Please use the search function below to find the hospital in which you are affiliated. Linking to your affiliated hospital will allow your Authorized Representative to track the completion of your training and Knowledge Assessment.

|                                    |        |                      |         |                      |        |
|------------------------------------|--------|----------------------|---------|----------------------|--------|
| Zip Code                           | - or - | City                 | - and - | State                | Search |
| <input type="text" value="10201"/> |        | <input type="text"/> |         | <input type="text"/> |        |

Show 10 entries

| Name   | Address         | City     | State | Zip Code |
|--|-----------------|----------|-------|----------|
| <input type="radio"/> Floyd Valley Hospital                          | 890 Main Street | New York | NY    | 10201    |
| <input checked="" type="radio"/> Health & Hospital Corp of Marion Co | 15 Park Avenue  | New York | NY    | 10201    |

1 - 2 of 2 items

I cannot find my Hospital location.

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## 21. Education Landing Page for Hospital

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✓ Thank you! Your intake was successful.

To review the tools for healthcare provider training and patient education for IONSYS please use the **Start** button when you are ready to begin.

### Education Resources Overview

The IONSYS REMS tools for healthcare provider training and patient education include:

- *IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists*
- *IONSYS Instructions for Use and Disposal*
- *IONSYS Guide for Patients*
- [Full Prescribing Information](#)

Start

## 22. Education Landing Page for Nurses and Pharmacists

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✔ Thank you! You have successfully linked your account to a Hospital.

To review the tools for healthcare provider training and patient education for IONSYS please use the **Start** button when you are ready to begin.

[Education Resources Overview](#)

The IONSYS REMS tools for healthcare provider training and patient education include:

- IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists
- IONSYS Instructions for Use and Disposal
- IONSYS Guide for Patients
- [Full Prescribing Information](#)

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## 23. Header of the Education Page and Knowledge Assessment for Hospital

- If Hospital Authorized Representative is taking the Education Program and Knowledge Assessment the **Hospital Certification** tab will be highlighted as shown below.

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## 24. Header of the Education Page and Knowledge Assessment for Nurses and Pharmacists

- If Nurses and Pharmacists are taking the Education Program and Knowledge Assessment the **Healthcare Providers** tab will be highlighted as shown below.

Note: For the purpose of the mockup document, the header for Education page and Knowledge Assessment will display with Hospital Certification tab.

## 25. Education Page 1

### IONSYS® REMS Safety Brochure: Guide For Nurses and Pharmacists

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 in adult patients requiring opioid analgesia **in a hospital**. 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.

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### IONSYS® REMS Safety Brochure: Guide For Nurses and Pharmacists (continued)

#### 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.

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## 27. Education Page 3

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### IONSYS® REMS Safety Brochure: Guide For Nurses and Pharmacists (continued)

#### 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 Guide for Patients* (included with each IONSYS)
  - 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

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## 28. Education Page 4

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### IONSYS® REMS Safety Brochure: Guide For Nurses and Pharmacists (continued)

#### 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

**Dear Healthcare Provider Letters:** Intended for Hospital Heads of Pharmacy, Nursing, General Surgery, Anesthesia, Obstetrics and Gynecology, and Orthopedics at certified hospitals.

**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](http://www.IONSYSREMS.com)).

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## 29. Education Page 5

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### IONSYS® REMS Safety Brochure: Guide For Nurses and Pharmacists (continued)

#### Other IONSYS Materials

**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 trouble shoot any problems with IONSYS. This IFUD is included with each IONSYS and on the IONSYS REMS website.

**IONSYS Guide for Patients:** 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.

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

#### 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](http://www.IONSYSREMS.com) or toll free at 1-877-488-6835.

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 100

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### Instructions for Use and Disposal

#### IONSYS®

fentanyl iontophoretic transdermal system, 40mcg/activation

For single use only. Up to 24 hours or 80 doses, whichever comes first.

Refer to the **Prescribing Information (PI)** and the following educational materials for more information about IONSYS:

- [IONSYS Guide for Patients](#)
- [IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists](#)



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## 31. Education Page 7

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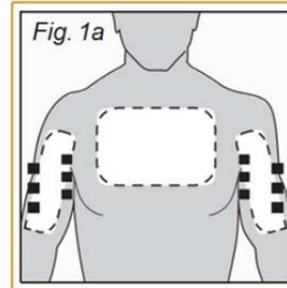
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### Instructions for Use and Disposal (continued)

#### 1. Prepare Patient Site

▲ ONLY 1 IONSYS system should be applied at any given time.

- Choose healthy, unbroken skin on the upper outer arm or chest **ONLY** (see Figure 1a).
- Clip excessive hair if necessary. **Do not shave—this irritates skin.**
- Clean with alcohol and let dry. **Do not use soaps, lotions, or other agents.**
- When replacing an IONSYS system, the new system must be applied to a different site on the upper outer arm or chest.



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### Instructions for Use and Disposal (continued)

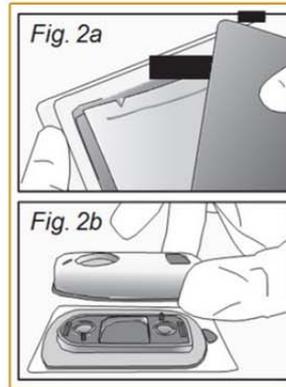
#### 2. Assemble IONSYS

**▲ Always wear gloves when handling IONSYS.**

**▲ Complete this step before applying IONSYS to patient.**

- a. Peel back tray lid (see Figure 2a). Remove foil pouch and the controller.
- b. Remove drug unit from foil pouch and place on a hard, flat surface (see Figure 2b).

Continued on next panel.



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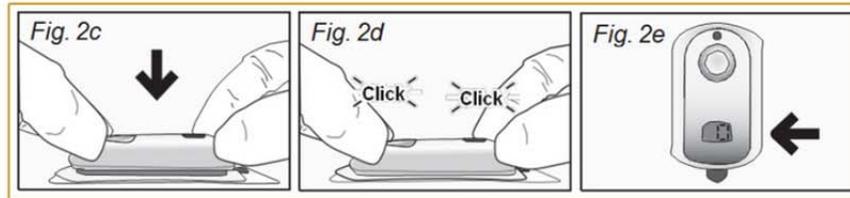
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### Instructions for Use and Disposal (continued)

#### 2. Assemble IONSYS (cont.)

- c. Align the matching shapes (see Figure 2c).
- d. Press on both ends of the device to ensure that snaps at both ends are fully engaged (see Figure 2d).
- e. Wait for system to complete self-test and the digital display to read "0" (see Figure 2e).



#### 3. Train Patient on Proper Use of IONSYS

- ▲ Refer to the **IONSYS Guide for Patients** to counsel your patient on the safe use of IONSYS.

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## 34. Education Page 10

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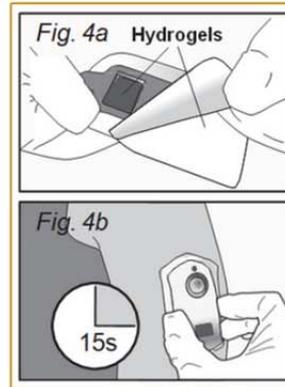
### Instructions for Use and Disposal (continued)

#### 4. Apply IONSYS to Patient

**▲ Always wear gloves when handling IONSYS.**

- Peel off clear liner and apply IONSYS to the prepared site (see Figure 4a).
- Press and hold IONSYS onto patient for **15 seconds** by pressing the edges with fingers (see Figure 4b). **Do not press dosing button.**
- If IONSYS is not securely adhered, see IONSYS Troubleshooting – Poor skin contact.

NOTE: Ensure proper display orientation by reading "Doses Delivered" printed below the digital display.



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### Instructions for Use and Disposal (continued)

#### 5. Verify Proper Use of IONSYS

- ▲ Remember that **ONLY** the patient should press the dosing button.
- ▲ Remove before MRI or radiographic procedures as medically necessary.
- Patient will initiate a dose by pressing and releasing the button twice in 3 seconds
- Each dose will be delivered over 10 minutes. During this time IONSYS is locked-out and will not respond to additional button presses
- During the 10 minutes the light will blink green at a fast rate and the display will alternate between a walking circle and the number of doses delivered (see Figure 5)



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### Instructions for Use and Disposal (continued)

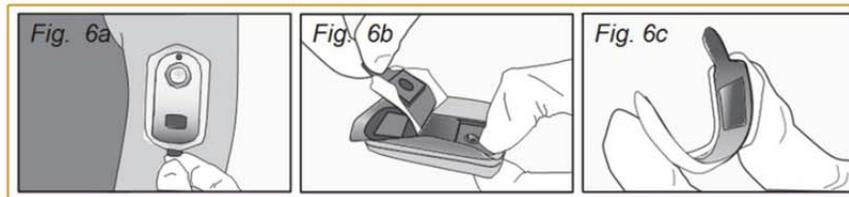
#### 6. Remove IONSYS from Patient and Dispose

▲ Follow your institution's procedures for handling narcotics or refer to the PI for more information.

▲ Always wear gloves when handling IONSYS.

▲ Important: If drug gel contacts your skin, thoroughly rinse area with water. Do not use soap.

- With gloves on, remove IONSYS from the patient (see Figure 6a).
- Pull the red tab to separate the red housing containing the drug (see Figure 6b).
- Fold the red housing in half and dispose per your institution's procedures or flush down the toilet (see Figure 6c).
- Hold down dosing button until display goes blank and dispose in waste designated for batteries.



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### Instructions for Use and Disposal (continued)

#### IONSYS Troubleshooting

After successful assembly or anytime during use:

| If you see or hear this...   | ...then do this:  |
|--|---|
| <p>Blinking red for 15 seconds</p> <p>Beeping for 15 seconds</p> <p>Steady number</p> <p>IONSYS is not securely adhered</p>  <p>Tape along long edges</p>  | <p><b>Poor Skin Contact</b></p> <ol style="list-style-type: none"><li>If IONSYS appears to be loose or lifting from skin, secure it to patient's skin by pressing the edges with fingers or securing with nonallergenic tape.</li><li>If using tape, apply it along the long edges to secure IONSYS to patient's skin.<br/><b>Do not cover the button or display.</b></li><li>After taping, if IONSYS beeps again, remove and dispose. Place a <b>new</b> IONSYS on a <b>different</b> skin site.</li><li><b>Do not tape if evidence of blistered or broken skin.</b></li></ol> |
| <p>No light</p> <p>No beeps</p> <p>Blank display</p>   | <p><b>Low Battery or Defective System</b></p> <ol style="list-style-type: none"><li><b>Do not use the system.</b></li><li>Dispose of IONSYS per instructions in section 6.</li><li>Place a <b>new</b> IONSYS on a <b>different</b> skin site.</li></ol>   |
| <p>Blinking red</p> <p>Beeping continuously</p> <p>Steady number</p>    | <p><b>System Error</b></p> <ol style="list-style-type: none"><li>Remove from patient.</li><li>Hold down dosing button until beeping stops and display goes blank.</li><li>Dispose of IONSYS per instructions in section 6.</li><li>Place a <b>new</b> IONSYS on a <b>different</b> skin site.</li></ol>   |
| <p>No light</p> <p>No beeps</p> <p>Blinking number</p>    | <p><b>End-of-Use (80 doses or 24 hours)</b></p> <ol style="list-style-type: none"><li>Remove from patient.</li><li>Hold down dosing button until display goes blank.</li><li>Dispose of IONSYS per instructions in section 6.</li><li>Place a <b>new</b> IONSYS on a <b>different</b> skin site.</li></ol>  |

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### IONSYS Guide for Patients

#### Important:

- IONSYS is only for use in the hospital. Do not leave the hospital with an IONSYS on your skin
- IONSYS can cause life-threatening breathing problems or death if it is used other than described in the section "How do I use IONSYS?" below
- Keep the IONSYS out of the reach of children

#### IONSYS:

- Contains the prescription medicine, fentanyl. Fentanyl is a very strong narcotic pain medicine (opioid)
- Is only used in the hospital for adults with short-term pain after surgery
- Is a patient-controlled medicine system that sticks to the skin. It will be applied by your healthcare provider on your upper outer arm or chest

#### Do not use IONSYS if you are allergic to:

- Fentanyl
- Cepacot (cetylpyridinium chloride)

#### Parts of the IONSYS system:



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### IONSYS Guide for Patients (continued)

#### Your healthcare provider:

- Will tell you about IONSYS and teach you how to use it
- Will put an IONSYS on your skin (on your upper outer arm or chest) after your surgery
- Will control pain from your surgery with other pain medicines until you are awake enough to use IONSYS
- Will check you for side effects from IONSYS
- Must replace your IONSYS as needed. You should not replace your IONSYS yourself
- Will remove your IONSYS before you leave the hospital. **Do not leave the hospital with an IONSYS on your skin**

#### How do I use IONSYS?

- You can push the IONSYS dosing button when you need to control your pain or just before you do an activity that may increase your pain such as physical therapy or getting out of bed
- To get a dose of pain medicine from IONSYS, **press and release the dosing button twice within 3 seconds**
- When you push the dosing button you will hear a single beep and the green light will start blinking quickly. The green light will continue to blink quickly for the 10 minutes it takes to deliver a dose of IONSYS
- During this time, IONSYS will not deliver another dose even if you press the dosing button again
- IONSYS can only be activated every 10 minutes
- When IONSYS is finished delivering a dose, the green light will start blinking slowly. This means you can give yourself more pain medicine, if needed. Just press and release the dosing button twice within 3 seconds like you did before. The digital display will tell your healthcare provider how many doses you have received. Each IONSYS may be used for up to 24 hours or a maximum of 80 doses, whichever comes first
- If IONSYS starts beeping at any time tell your healthcare provider right away



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### IONSYS Guide for Patients (continued)

#### Tell your healthcare provider right away if:

- You have any questions about IONSYS
- You are still having pain
- IONSYS falls off your skin
- You have trouble using IONSYS. Your healthcare provider will check your IONSYS to make sure it is working

#### Do not:

- Do not let anyone else press the IONSYS dosing button for you. **You are the only person who should push the dosing button**
- Do not touch IONSYS if it falls off of your skin. Tell your healthcare provider right away if your IONSYS comes off of your skin. Rinse your hands with water (do not use soap) right away if you accidentally touch the sticky side of IONSYS, and tell your healthcare provider right away
- Do not let others touch IONSYS
- Do not remove or replace IONSYS yourself
- Do not leave the hospital with an IONSYS on your skin. **Make sure your healthcare provider removes your IONSYS before you leave the hospital**

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## 41. Knowledge Assessment Landing Page

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### Knowledge Assessment

You are now going to review questions that will test your knowledge of the appropriate use of IONSYS® (fentanyl iontophoretic transdermal system) - including important risk messages associated with its safe use. To be certified in the IONSYSREMS Program you will need to answer ALL questions correctly. Please select the **best** option for each question.

Start Assessment

You will have a maximum of six attempts to pass the assessment. After three unsuccessful attempts, the education resources are required to be reviewed again before retaking the Knowledge Assessment.

## 42. Knowledge Assessment #1

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### Knowledge Assessment

#### Question 1

The IONSYS Risk Evaluation and Mitigation Strategy (REMS) is required by the Food and Drug Administration (FDA) to:

- A. Prevent respiratory depression resulting from accidental exposure to persons for whom it is not prescribed
- B. Educate healthcare providers about the risk of respiratory depression associated with IONSYS
- C. Ensure that IONSYS is dispensed and administered only within hospitals
- D. All of the above

Next

## 43. Knowledge Assessment #2

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### Knowledge Assessment

#### Question 2

It is important that only healthcare providers are educated about the safe use of IONSYS.

- A. True
- B. False

Next

## 44. Knowledge Assessment #3

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### Knowledge Assessment

#### Question 3

IONSYS may be sent home with the patient upon leaving the hospital.

- A. True
- B. False

Next

## 45. Knowledge Assessment #4

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### Knowledge Assessment

#### Question 4

Healthcare providers (nurses and pharmacists) should avoid contact with the IONSYS hydrogel (i.e., wear gloves) when:

- A. Applying IONSYS
- B. Monitoring Patient Use of IONSYS
- C. Removing IONSYS
- D. Disposing of IONSYS
- E. All of the above

Next

## 46. Knowledge Assessment #5

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### Knowledge Assessment

#### Question 5

The *IONSYS Guide for Patients* contains important information for the patient. Which one of the following statements is accurate?

- A. The IONSYS REMS Program will provide this guide to patients by mail after a patient has left the hospital
- B. This guide only needs to be reviewed with the patient's caregiver before initiating treatment with IONSYS, because the patient may not be able to understand the instructions for use
- C. This guide should be reviewed with patients and caregivers before initiating treatment with IONSYS
- D. The *IONSYS Guide for Patients* can only be obtained from hospital pharmacies

Next

## 47. Knowledge Assessment #6

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### Knowledge Assessment

#### Question 6

There is a risk of fatal overdose with inappropriate use or handling of IONSYS. Which of the following answers is most accurate?

- A. IONSYS can be fatal if misused by children
- B. IONSYS can be fatal if used by anyone for whom it is not prescribed
- C. IONSYS can be fatal if the hydrogels are ingested or if they come into contact with a healthcare provider's or patient's mucous membranes
- D. All of the above

Next

## 48. Knowledge Assessment #7

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### Knowledge Assessment

#### Question 7

Which of the following statements is accurate regarding safe disposal of IONSYS?

- A. IONSYS units should be removed using gloves - assuring both hydrogels remain with the unit
- B. The bottom housing containing the gels should be separated from the electronics (top housing) by pulling the red tab, and the bottom should be folded in half with the sticky side facing in. It should be disposed by flushing down the toilet or following institutional procedures
- C. Disposal of IONSYS should comply with hospital operating policies and procedures
- D. All of the above

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## 49. Knowledge Assessment #8

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### Knowledge Assessment

#### Question 8

Which of the following factors increases the risk of overdose of fentanyl from IONSYS?

- A. Instructing someone other than the patient to administer doses from IONSYS
- B. The patient must press the dose button twice within 3 seconds to administer a dose from IONSYS
- C. Applying only one IONSYS to a patient at any time
- D. IONSYS should only be applied to patients who can understand how to use IONSYS without help

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## 50. Knowledge Assessment #9

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### Knowledge Assessment

#### Question 9

What action is most likely to prevent IONSYS from being used outside of the hospital?

- A. Having inadequate record keeping of IONSYS dispensing
- B. Removing IONSYS from the patient prior to leaving the hospital
- C. Having inadequate hospital procedures for IONSYS disposal
- D. Applying IONSYS to the upper, outer arm, or chest

Submit

## 51. Knowledge Assessment – Success Page for Hospital

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### Knowledge Assessment Results

✔ Congratulations! You have now completed the assessment.

You answered all the questions correctly and have passed the assessment. Please press the **Next** button to complete your hospital's certification in the IONSYS REMS Program.

**Knowledge Assessment Code:** 1425-F545-S89P 🖨️

#### QUESTION 1

The IONSYS Risk Evaluation and Mitigation Strategy (REMS) is required by the Food and Drug Administration (FDA) to:

✔ D. All of the above

#### QUESTION 2

It is important that only healthcare providers are educated about the safe use of IONSYS.

✔ B. False

#### QUESTION 3

IONSYS may be sent home with the patient upon leaving the hospital.

✔ B. False

Next

## 52. Knowledge Assessment – Success Page for Nurses and Pharmacists

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### Knowledge Assessment Results

✔ Congratulations! You have now completed the assessment.

You answered all the questions correctly and have passed the assessment. Below is your IONSYS REMS Program Knowledge Assessment Code.

You and your Hospital Authorized Representative (if applicable) will receive an email confirmation

**Knowledge Assessment Code: 1545-H454-P545** 📧

#### QUESTION 1

The IONSYS Risk Evaluation and Mitigation Strategy (REMS) is required by the Food and Drug Administration (FDA) to:

✔ D. All of the above

#### QUESTION 2

It is important that only healthcare providers are educated about the safe use of IONSYS.

✔ B. False

#### QUESTION 3

IONSYS may be sent home with the patient upon leaving the hospital.

✔ B. False

## 53. Knowledge Assessment – Failed Attempt Page

Note: For the purpose of the mockup document the header will display with Hospital Certification tab; however, depending on the stakeholder type the appropriate tab will be highlighted.

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### Knowledge Assessment Results

**We're sorry, you did not pass the Knowledge Assessment.**

Below is a summary of your response. After three failed attempts, you must review the IONSYS REMS education resources before retaking the assessment. You have a maximum of six attempts to pass the assessment. Please use the **Retake Assessment** button below to correct your answers. Alternatively, you may revisit the IONSYS REMS education resources then take the assessment again.

**QUESTION 1**

The IONSYS Risk Evaluation and Mitigation Strategy (REMS) is required by the Food and Drug Administration (FDA) to:

✓ D. All of the above

**QUESTION 2**

It is important that only healthcare providers are educated about the safe use of IONSYS.

✗ B. True

**QUESTION 3**

IONSYS may be sent home with the patient upon leaving the hospital.

✓ B. False

ATTEMPT 1 ██████████

Education Resources Retake Assessment

## 54. Knowledge Assessment – Failed 3<sup>rd</sup> Attempts

Note: For the purpose of the mockup document the header will display with Hospital Certification tab; however, depending on the stakeholder type the appropriate tab will be highlighted.

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### Knowledge Assessment Results

We're sorry, you did not pass the Knowledge Assessment.

Below is a summary of your response. You must review the IONSYS REMS education resources again before you attempt to retake the Knowledge Assessment. Please use the **Education Resources** button to review the education resources. Once your review is complete, you can retake the assessment again.

#### QUESTION 1

The IONSYS Risk Evaluation and Mitigation Strategy (REMS) is required by the Food and Drug Administration (FDA) to:

✓ D. All of the above

#### QUESTION 2

It is important that only healthcare providers are educated about the safe use of IONSYS.

✗ B. True

#### QUESTION 3

IONSYS may be sent home with the patient upon leaving the hospital.

✓ B. False

ATTEMPT **1 2 3** 4 5 6

Education Resources

## 55. Knowledge Assessment – Failed 6<sup>th</sup> Attempts

*Note: For the purpose of the mockup document the header will display with Hospital Certification tab; however, depending on the stakeholder type the appropriate tab will be highlighted.*

The mockup displays the IONSYS logo (fentanyl iontophoretic transdermal system) in the top left. In the top right, it shows the user name 'Frank Adam' and a 'My Dashboard' button. Below the logo is a navigation bar with tabs: 'Home', 'Patient Information', 'Hospital Certification' (highlighted), 'Healthcare Providers', and 'Forms & Resources'. Underneath the navigation bar is the heading 'Knowledge Assessment Results'. A red-bordered box contains the message: 'We're sorry, you did not pass the Knowledge Assessment.' Below this, a paragraph explains that the user's ability to take the assessment has been suspended after six failed attempts and provides contact information for the IONSYS REMS Program. At the bottom of the notification area, there is a visual progress indicator for 'ATTEMPT' with six numbered boxes, where the sixth box is highlighted in red.

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### Knowledge Assessment Results

**We're sorry, you did not pass the Knowledge Assessment.**

Because this was your sixth failed attempt at the Knowledge Assessment your ability to take the Knowledge Assessment has been suspended.  
In order to reset your Knowledge Assessment attempts you must contact the IONSYS REMS Program at 877-488-6835.

ATTEMPT 1 2 3 4 5 6

## 56. Hospital Attestation

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### Hospital Attestation

To complete the certification for [Health & Hospital Corp of Marion Co](#) into the IONSYS REMS Program online, please review the attestation section below to provide your acknowledgement along with signature and signature date.

Alternatively, you may print your online enrollment form and fax it to the IONSYS REMS Program at 877-488-6835. 📠

As an Authorized Representative responsible for the hospital, I, **Frank Adam**, attest to the following IONSYS REMS Program requirements:

I understand that IONSYS is only available through the IONSYS REMS Program. As the designated Authorized Representative, I must comply with the following program requirements for hospitals to ensure that IONSYS is only ordered, prescribed, dispensed, and administered in certified hospitals. I acknowledge that:

1. I am the Authorized Representative designated by my hospital to complete certification on behalf of the hospital and oversee implementation and compliance with the IONSYS REMS Program.
2. I attest that this hospital provides acute care, treats patients in the hospital, and offers post-operative pain management.
3. I have reviewed the IONSYS Prescribing Information, *IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists* (to which the *IONSYS Instructions for Use and Disposal* and the *IONSYS Guide for Patients* are attached), and I have successfully completed the *IONSYS REMS Knowledge Assessment*.
4. I understand the benefits and risks associated with IONSYS and the requirements of the IONSYS REMS Program.
5. I will ensure all staff, including pharmacy and nursing staff, involved in dispensing or administering IONSYS have been trained on the IONSYS REMS Program requirements as described in the *IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists* (to which the *IONSYS Instructions for Use and Disposal* and the *IONSYS Guide for Patients* are attached) and have successfully completed the *IONSYS REMS Knowledge Assessment*. This training will be documented.
6. I will establish or oversee the processes, procedures, systems, order sets, protocols, and/or other measures to help ensure compliance with the requirements of the IONSYS REMS Program. These processes, procedures, and/or other measures will be documented.
7. I understand that the hospital will not sell, loan, or transfer IONSYS inventory to any other pharmacy, institution, distributor, or prescriber.
8. I will ensure that the certified hospital involved in the prescribing, dispensing, and administration of IONSYS are informed of risks of respiratory depression and the elements of the IONSYS REMS by distributing the Dear Healthcare Provider Letters and Dear Hospital Pharmacy Letter within 3 weeks of receiving notification of certification in the IONSYS REMS Program.
9. I understand that the hospital pharmacy is not to dispense IONSYS for use outside the hospital.
10. I understand that IONSYS must be removed from the patient prior to the patient leaving the hospital.
11. I will report any adverse events suggestive of respiratory depression resulting from accidental exposure associated with the use of IONSYS to The Medicines Company or the FDA.
12. I will comply with requests to be audited by The Medicines Company to ensure that all processes and procedures are in place and are being followed for the IONSYS REMS Program and appropriate documentation is available upon request.
13. I will renew this hospital's certification in the IONSYS REMS Program every 3 years after initial certification.
14. I understand this hospital must have a new Authorized Representative complete an *IONSYS REMS Hospital Enrollment Form* and successfully complete the *IONSYS REMS Knowledge Assessment* within 4 weeks of the hospital designating a new Authorized Representative.

By checking this box, I agree to the responsibility outlined above and hereby state that all of the information I have submitted is truthful and accurate.

Signature

Signature Date

Cancel

Submit

## 57. My Dashboard – View Hospitals

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### My Dashboard

Welcome to your IONSYS REMS Program dashboard.

[View Hospitals](#)

[View Nurses and Pharmacists](#)

Below is/are your Hospital location(s) certification details. Please use the **Add Hospital** button to add a new hospital location.

Show 10 ▾ entries

| Name                                | Address                               | Certification ID | Certification Status | Certified Date | Expiration Date | Actions                    |
|-------------------------------------|---------------------------------------|------------------|----------------------|----------------|-----------------|----------------------------|
| Health & Hospital Corp of Marion Co | 15 Park Avenue, New York NY 10201     | FAC849482299     | Certified            | 03/15/2015     | 03/15/2018      | <a href="#">View</a>       |
| Floyd Valley Hospital               | 890 Main Street, Phoenix AZ 84747     | FAC849484848     | Incomplete           |                |                 | <a href="#">Resume</a>     |
| Western State Hospital              | 24E 77th Street, Los Angeles CA 90027 | FAC845656656     | Deactivated          | 03/15/2015     | 07/27/2015      | <a href="#">Re-certify</a> |

1 - 3 of 3 items

Add Hospital



## 58. My Dashboard – View Nurses and Pharmacists

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### My Dashboard

Welcome to your IONSYS REMS Program dashboard.

[View Hospitals](#) [View Nurses and Pharmacists](#)

Below are the nurses and pharmacists associated with your Hospital location(s) along with their Knowledge Assessment status. Please use the **Add Nurses and Pharmacists** button to affiliate a new nurse and/or pharmacist.

Show  entries

| Name       | Hospital Name                       | Hospital Address                  | Knowledge Assessment Information |                |                 |                 |
|------------|-------------------------------------|-----------------------------------|----------------------------------|----------------|-----------------|-----------------|
|            |                                     |                                   | Status                           | Code           | Completion Date | Expiration Date |
| John Doe   | Health & Hospital Corp of Marion Co | 15 Park Avenue, New York NY 10201 | Complete                         | 1425-F545-S89P | 05/15/2015      | 05/15/2018      |
| John Smith | Floyd Valley Hospital               | 890 Main Street, Phoenix AZ 84747 | Incomplete                       |                |                 |                 |

1 - 2 of 2 items

**Add Nurses and Pharmacists** 

## 59. My Dashboard – View Nurses and Pharmacists with Add Nurses and Pharmacists Functionality

### My Dashboard

Welcome to your IONSYS REMS Program dashboard.

[View Hospitals](#) [View Nurses and Pharmacists](#)

Below are the nurses and pharmacists associated with your Hospital location(s) along with their Knowledge Assessment status. Please use the **Add Nurses and Pharmacists** button to affiliate a new nurse and/or pharmacist.

Show 10 entries

| Name       | Hospital Name                       | Hospital Address                  | Knowledge Assessment Information |                |                 |                 |
|------------|-------------------------------------|-----------------------------------|----------------------------------|----------------|-----------------|-----------------|
|            |                                     |                                   | Status                           | Code           | Completion Date | Expiration Date |
| John Doe   | Health & Hospital Corp of Marion Co | 15 Park Avenue, New York NY 10201 | Complete                         | 1425-F545-S89P | 05/15/2015      | 05/15/2018      |
| John Smith | Floyd Valley Hospital               | 890 Main Street, Phoenix AZ 84747 | Incomplete                       |                |                 |                 |

1 - 2 of 2 items

[Add Nurses and Pharmacists](#)

### Add Nurses and Pharmacists

To add affiliate nurses and/or pharmacists to your Hospital, please enter their Knowledge Assessment Confirmation Code and press **Search**. If your search results contain the nurses or pharmacists you were looking for, please use the **Add** button to affiliate them to your hospital.

Knowledge Assessment Confirmation Code  [Search](#)

| Knowledge Assessment Code | Name     | Address                             | Phone        |
|---------------------------|----------|-------------------------------------|--------------|
| 1425-F545-S89P            | John Doe | 123 Main Street, New York, NY 10001 | 555-555-5555 |

1 - 1 of 1 items

[Remove](#)

[Add](#)

## 60. Hospital Certification Progress – Certified

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My Dashboard

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|      |                     |                        |                      |                   |
|------|---------------------|------------------------|----------------------|-------------------|
| Home | Patient Information | Hospital Certification | Healthcare Providers | Forms & Resources |
|------|---------------------|------------------------|----------------------|-------------------|

Health & Hospital Corp of Marion Co

From the table below you can view and track your certification progress for the hospital.

| Activity                  | Progress    | Action                                       |
|---------------------------|-------------|--|
| Account Registration      | ✓ Completed |  |
| Enrollment Form           | ✓ Completed |  |
| Education Resources       | ✓ Completed | <a href="#">Download Education Resources</a> |
| Knowledge Assessment      | ✓ Completed |  |
| Certification Attestation | ✓ Completed | <a href="#">Print Confirmation</a>           |
| My Profile                | ✓ Available | <a href="#">View</a>                         |

## 61. Hospital Certification Progress – Incomplete Certification

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|      |                     |                        |                      |                   |
|------|---------------------|------------------------|----------------------|-------------------|
| Home | Patient Information | Hospital Certification | Healthcare Providers | Forms & Resources |
|------|---------------------|------------------------|----------------------|-------------------|

Floyd Valley Hospital

From the table below you can view and track your certification progress for the hospital.

| Activity                  | Progress    | Action                                  |
|---------------------------|-------------|---|
| Account Registration      | ✓ Completed |   |
| Enrollment Form           | Incomplete  | <a href="#">Edit Enrollment Form</a>    |
| Education Resources       | Incomplete  | <a href="#">Start Education Program</a> |
| Knowledge Assessment      | Incomplete  |   |
| Certification Attestation | Incomplete  |   |
| My Profile                | ✓ Available | <a href="#">View</a>                    |

## 62. Nurses and Pharmacists Progress – KA Incomplete

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|      |                     |                        |                      |                   |
|------|---------------------|------------------------|----------------------|-------------------|
| Home | Patient Information | Hospital Certification | Healthcare Providers | Forms & Resources |
|------|---------------------|------------------------|----------------------|-------------------|

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From the table below you can view and track your progress.

| Activity             | Progress    | Action                                  |
|----------------------|-------------|---|
| Account Registration | ✓ Completed |   |
| Education Resources  | Incomplete  | <a href="#">Start Education Program</a> |
| Knowledge Assessment | Incomplete  |   |

## 63. Nurses and Pharmacists Progress – KA Completed

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|      |                     |                        |                      |                   |
|------|---------------------|------------------------|----------------------|-------------------|
| Home | Patient Information | Hospital Certification | Healthcare Providers | Forms & Resources |
|------|---------------------|------------------------|----------------------|-------------------|

Frank Adam

From the table below you can view and track your progress.

| Activity             | Progress    | Action                                       |
|----------------------|-------------|--|
| Account Registration | ✓ Completed |  |
| Education Resources  | ✓ Completed | <a href="#">Download Education Resources</a> |
| Knowledge Assessment | ✓ Completed | <a href="#">Print Confirmation</a>           |

## 64. Hospital Certification Confirmation

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### Certification Confirmation

**Congratulations! Your hospital is now certified in the IONSYS REMS Program.**

Below is your IONSYS REMS Program Certification ID. Please retain this information for your records.

**Certification ID: FAC847474** 🖨️

You may now:

- [Manage your hospitals](#)
- [View your profile](#)

## 65. Authorized Representative Profile

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### Authorized Representative Profile

Your profile information is displayed below. If you need to make any changes to your profile please contact the IONSYS REMS Program at 877-488-6835. To go back to your Dashboard please use the **My Dashboard** button in the top right corner of this website.

|                                   |                       |
|-----------------------------------|-----------------------|
| Name                              | <First and Last Name> |
| Title                             | <b>Nurse</b>          |
| Phone                             | <b>898-938-8484</b>   |
| Ext                               | <b>8558</b>           |
| Fax                               | <b>585-383-3838</b>   |
| Email                             | <email address>       |
| Preferred Method of Communication | <b>Email</b>          |

## 66. Forms & Resources

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Username  Password  [Sign in](#)

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

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[Home](#)

[Patient Information](#)

[Hospital Certification](#)

[Healthcare Providers](#)

[Forms & Resources](#)

### Forms & Resources

#### Forms

 [IONSYS REMS Hospital Enrollment Form](#)

#### Resources

 [IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists](#)

 [IONSYS REMS Knowledge Assessment](#)

 [Dear Healthcare Provider Letter - Department Head: Surgery](#)

 [Dear Healthcare Provider Letter - Department Head: Anesthesia](#)

 [Dear Healthcare Provider Letter - Department Head: Nursing](#)

 [Dear Healthcare Provider Letter - Department Head: Obstetrics and Gynecology](#)

 [Dear Healthcare Provider Letter - Department Head: Orthopedics](#)

 [Dear Hospital Pharmacy Letter](#)

 [IONSYS Instructions for Use and Disposal](#)

 [IONSYS Guide for Patients](#)

 [Full Prescribing Information](#)

## 67. Request Username

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[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Important Safety Information](#) | [Full Prescribing Information](#)

|                      |                                     |  |                                      |                                       |
|----------------------|-------------------------------------|--|--------------------------------------|---------------------------------------|
| <a href="#">Home</a> | <a href="#">Patient Information</a> | <a href="#">Hospital Certification</a> | <a href="#">Healthcare Providers</a> | <a href="#">Forms &amp; Resources</a> |
|----------------------|-------------------------------------|--|--------------------------------------|---------------------------------------|

### Request Username

Please enter your credentials in the spaces provided below. Your username will be sent to your registered email address with the IONSYS REMS Program.

|               |                                       |
|---------------|---------------------------------------|
| First Name    | <input type="text"/>                  |
| Last Name     | <input type="text"/>                  |
| Email Address | <input type="text"/>                  |
|               | <input type="button" value="Submit"/> |

## 68. Request Password

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Username  Password  [Sign in](#)

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

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### Request Password

Please enter the username and email address you used to register in the IONSYS REMS Program below. You will receive an email with a temporary password. Please follow the instructions in the email to reset your password.

|               |                        |
|---------------|------------------------|
| Username      | <input type="text"/>   |
| Email Address | <input type="text"/>   |
|               | <a href="#">Submit</a> |

## 69. Change Password

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### Change Password

To change your password, please use the fields below. Your new password must be at least eight (8) characters in length and contain at least one letter and one number. Passwords are case sensitive.

|                      |                          |
|----------------------|--------------------------|
| Current Password     | <input type="password"/> |
| New Password         | <input type="password"/> |
| Confirm New Password | <input type="password"/> |
|                      | <a href="#">Submit</a>   |

## 70. Contact Us

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### Contact Us

If you have any questions or require additional information, please contact the IONSYS REMS Program utilizing the information provided below.

**Phone Number**

877-488-6835

**Fax Number**

877-488-8601

**Mailing Address**

IONSYS REMS Program  
P.O. BOX 29242  
PHOENIX, AZ 85038-9242

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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JUDITH A RACOOSIN  
11/12/2015

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