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Most recent modification: 10/2018

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 Medication Guide 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 Medication Guide are attached) and successfully complete the IONSYS REMS Knowledge Assessment, and understand the key risk messages for patients described in the IONSYS Medication Guide.
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 wholesalers/distributor to distribute IONSYS, the wholesalers/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 Medicines Company

ii. Ensuring that wholesalers/distributors maintain distribution records of all shipments of IONSYS and agree to provide the data to 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) or through the IONSYS REMS Program Call Center. The REMS program website will include the option to print the 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).

g. The Medicines Company will monitor and audit the certified hospitals within 90 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 within 14 days if noncompliance is identified and will include a re-audit of the certified hospital after 90 days of the corrective action to ensure all processes and procedures are in place and functioning to support the requirements of the IONSYS REMS Program. 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 severe enough to require an opioid analgesic in the hospital and for which alternative treatments are inadequate. IONSYS is a patient-controlled analgesia product that enables surgical patients to push a button to dispense fentanyl transdermally as needed for pain. Only the patient may activate IONSYS. Hospital pharmacies will not dispense IONSYS for outpatient use.

WHAT IS A REMS?

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

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

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

WHAT ARE THE ROLES OF NURSES AND PHARMACISTS IN THE SAFE USE OF IONSYS?

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

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

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

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

**ARE THERE INSTRUCTIONS ON HOW TO USE IONSYS?**

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

**HEALTHCARE PROVIDER EDUCATION AND TRAINING**

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

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

**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).

If you have any questions regarding IONSYS or the IONSYS REMS Program call 877-488-6835
OTHER IONSYS MATERIALS (Available on www.IONSYSREMS.com website)

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

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

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

OPTIONS FOR EDUCATION AND TRAINING

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

ADVERSE EVENT REPORTING

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

CONTACT INFORMATION FOR THE IONSYS REMS PROGRAM

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

Attachment A: IONSYS Medication Guide
Attachment B: IONSYS Instructions for Use and Disposal
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 Medication Guide**
- **IONSYS 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 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 via the **Healthcare Providers** tab.

### Hospital Authorized Representative, Nurse, or Pharmacist

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<td>DEA License Number (Authorized Representative only):</td>
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**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

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

If you have any questions regarding IONSYS or the IONSYS REMS Program call 877-488-6835
## IONSYS® REMS HOSPITAL ENROLLMENT FORM

All Fields Required Unless Otherwise Indicated.

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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 Prescribing Information, including Boxed Warnings.
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, Anesthesia:

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 severe enough to require an opioid analgesic in the hospital and for which alternative treatments are inadequate. 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 Medication Guide.
• 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 Medication Guide 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. Prescribing Information: This document provides the prescribing information for IONSYS (fentanyl iontophoretic transdermal system), which includes instructions for use and disposal. (It also includes the IONSYS Medication Guide as an attachment).


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

Reference ID: 4329753
5. **IONSYS REMS Hospital Enrollment Form**: IONSYS can only be ordered, dispensed, and administered in hospitals which are 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).

**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.

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.

This letter is not a comprehensive description of the risks associated with the use of IONSYS. Refer to the 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 for more information or call the toll-free number: 1-877-488-6835.

Sincerely,

The Medicines Company

Enclosures:

*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 Chief of Surgery:

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 severe enough to require an opioid analgesic in the hospital and for which alternative treatments are inadequate. 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 Medication Guide.
- 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 Medication Guide 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. Prescribing Information: This document provides the prescribing information for IONSYS (fentanyl iontophoretic transdermal system), which includes instructions for use and disposal. (It also includes the IONSYS Medication Guide as an attachment).

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).

### 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.

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- 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 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 severe enough to require an opioid analgesic in the hospital and for which alternative treatments are inadequate. 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.

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

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- **Prescribing Information**
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- **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 Department Head, Obstetrics and Gynecology:

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 severe enough to require an opioid analgesic in the hospital and for which alternative treatments are inadequate. 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.

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

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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 Department Head, Orthopedics:

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 severe enough to require an opioid analgesic in the hospital and for which alternative treatments are inadequate. 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.

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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:

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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:

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 severe enough to require an opioid analgesic in the hospital and for which alternative treatments are inadequate. 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 was certified in the IONSYS REMS Program.

SAFE USE OF IONSYS

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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:

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

**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,
- **serving** 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).

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Sincerely,

The Medicines Company

Enclosures:

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

Risk Evaluation and Mitigation Strategy

Website Mockups
V8.0
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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.
2. **Home Page**

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.

**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 Medication Guide (included with each IONSYS).
- Only the patient should administer doses from IONSYS.
- The IONSYS Hydrogel 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 leaking.
- 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 severe enough to require an opioid analgesic in the hospital and for which alternative treatments are inadequate. IONSYS is a patient-controlled analgesia product that enables surgical patients to push a button to dispense fentanyl transdermally as needed for pain. Only the patient may activate IONSYS. Hospital pharmacies will not dispense IONSYS for outpatient use.

**Resources for Healthcare Providers**

- IONSYS REMS Hospital Enrolment 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, Anesthesiology
- 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
- Prescribing Information

**Resources for Patients**

- IONSYS Medication Guide
3. Home Page – Signed-In

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 Medicine Company has worked with the FDA to develop the IONSYS REMS Program to mitigate this potential risk.

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 Medication Guide (included with each IONSYS):
  - Only the patient should administer doses from IONSYS.
  - The IONSYS hydrogel 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 bubbling.
  - 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 severe enough to require an opioid analgesic in the hospital and for which alternative treatments are inadequate. IONSYS is a patient-controlled analgesia product that enables surgical patients to push a button to dispense fentanyl transdermally, as needed for pain. Only the patient may activate IONSYS. Hospital pharmacies will not dispense IONSYS for outpatient use.

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
- Prescribing Information

Resources for Patients

- IONSYS Medication Guide
4. Patient Information

IONSYS®
(fentanyl iontophoretic transdermal system®)

IONSYS Medication Guide

What is IONSYS?

IONSYS is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage acute postoperative pain, when other pain treatments such as non-opioid pain medicines do not treat your pain well enough or you cannot tolerate them.
- An opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.
- 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.

Please click on this link to see the IONSYS Medication Guide describing how to use IONSYS and important risk messages.

For additional information about the IONSYS REMS Program, please call 877-488-6836.
5. Hospital Certification

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: Review the IONSYS REMS Program Information at REMS100.
- Educate: Successfully complete the IONSYS REMS Hospital Information Assessment.
- Assess: Complete and sign the IONSYS REMS Hospital Enrollment Form. The certification must be renewed every three (3) years.
- Attest: Distribute Dear Healthcare Provider Letters along with IONSYS REMS Program education materials to the following hospital departments: Surgery, Anesthesia, Nursing, Obstetrics, Gynecology, Orthopedics, and Pharmacy.
- Distribute: Train staff who dispense or administer IONSYS (nurses and pharmacists) and ensure that they complete the IONSYS REMS Knowledge Assessment.
- Maintain: 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 877-488-6601 or mail to IONSYS REMS Program PO. Box 29242, Phoenix, AZ 85048-9242.

Start Certification
6. Hospital Certification – Signed-In

![IONSYS REMS Website Mockups V8.0](image)

**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:

<table>
<thead>
<tr>
<th>Designate</th>
<th>Educate</th>
<th>Assess</th>
<th>Attest</th>
<th>Distribute</th>
<th>Train</th>
<th>Maintain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Designate an Authorized Representative for the hospital</td>
<td>Review the IONSYS REMS Program education materials</td>
<td>Assess the knowledge of the Authorized Representative</td>
<td>Complete the IONSYS REMS Program education materials</td>
<td>Distribute Dear Healthcare Provider Letters along with the IONSYS REMS Program education materials to the following hospital department heads: Surgery, Anesthesiology, Nursing, Obstetrics/Gynecology, Orthopedics, and Pharmacy</td>
<td>Train all staff who dispense or administer IONSYS (nurses and pharmacists) on the IONSYS REMS Program and ensure they complete the IONSYS REMS Knowledge Assessment</td>
<td>Maintain the list of healthcare providers trained in the IONSYS REMS Program</td>
</tr>
</tbody>
</table>

**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: Anesthesiology
- 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 Medication Guide

Prescribing information
7. Nurses and Pharmacists – Not Signed-In

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, troubleshooting, 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 adherence 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**
- Review the following IONSYS REMS Program education resources:
  - IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists
  - IONSYS Instructions for Use and Disposal
  - IONSYS Medication Guide
  - Prescribing Information

**Assess**
- Successfully complete the IONSYS REMS Knowledge Assessment

**Maintain**
- 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.
8. **Nurses and Pharmacists – Signed-In**

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:

<table>
<thead>
<tr>
<th>Educate</th>
<th>Assess</th>
<th>Maintain</th>
</tr>
</thead>
</table>
| Review the following IONSYS REMS Program education resources:  
IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists  
IONSYS Instructions for Use and Disposal  
IONSYS Medication Guide  
Prescribing Information | Successfully complete the [IONSYS REMS Knowledge Assessment](#) | 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 |
9. 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

Last Name

Email Address

Certification ID (Optional)

Username

Password

Confirm Password

Submit
10. Stakeholder Identification Page

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 for attesting 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 Medication Guide** 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.

Next
11. 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**
- **State License Type**
- **Phone**
- **Fax**
- **Email Address**
- **Preferred Method of Communication**
  - Email
  - Fax

**Hospital Intake**

- **Hospital Name**
- **Hospital Address**
- **Hospital Address 2**
- **Hospital City**
- **Hospital State**
- **Hospital Zip**
- **State Hospital License Number**
- **Hospital DEA Number**
- **DEA License Expiration**

[Submit]
12. 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
Last Name
State License Number
State License Type
Phone
Fax
Email Address
Preferred Method of Communication

Enter the form data and submit it.
13. Hospital Lookup for Nurses and Pharmacists

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
14. Hospital Lookup for Nurses and Pharmacists with Search Result

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
10201

City
- or -

State

Search

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>City</th>
<th>State</th>
<th>Zip Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Floyd Valley Hospital</td>
<td>690 Main Street</td>
<td>New York</td>
<td>NY</td>
<td>10201</td>
</tr>
<tr>
<td>Health &amp; Hospitals Corp of Marion Co</td>
<td>10 Park Avenue</td>
<td>New York</td>
<td>NY</td>
<td>10201</td>
</tr>
</tbody>
</table>

1 - 2 of 2 items

I cannot find my hospital location.
15. Education Landing Page for 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 following IONSYS REMS tools will be included within this online healthcare provider training:

- IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists
- IONSYS instructions for Use and Disposal

Click on the links below to review the following documents prior to starting the Knowledge Assessment:

- IONSYS Medication Guide
- Prescribing Information

For additional information about the IONSYS REMS Program, please call 877-488-6835.
16. Education Landing Page for Nurses and Pharmacists

The following IONSYS REMS tools will be included within this online healthcare provider training:

- IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists
- IONSYS Instructions for Use and Disposal

Click on the links below to review the following documents prior to starting the Knowledge Assessment:

- IONSYS Medication Guide
- Prescribing Information

17. 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.

18. 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.

19. 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 severe enough to require an opioid analgesic in the hospital and for which alternative treatments are inadequate. IONSYS is a patient-controlled analgesia product that enables surgical patients to push a button to dispense fentanyl transdermally as needed for pain. Only the patient may activate IONSYS. Hospital pharmacies will not dispense IONSYS for outpatient use.

What is a REMS?
A Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage known or potential serious risks associated with a drug and is required by the US Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks. Treatment with fentanyl, the active component of IONSYS, may result in potentially life-threatening respiratory depression and death. The Medicines Company has worked with the FDA to develop the IONSYS REMS to prevent such respiratory depression resulting from accidental exposure to persons for whom it is not prescribed.

Educating nurses, pharmacists, and other healthcare providers about the risk of respiratory depression resulting from accidental exposure associated with IONSYS and ways this risk can be mitigated is an important part of this REMS. The IONSYS REMS also requires that hospitals be certified in the IONSYS REMS Program in order to dispense IONSYS.
20. Education Page 2

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 anaggesic 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.
21. Education Page 3

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 Medication Guide (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 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.
22. Education Page 4

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


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).
23. Education Page 5

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 troubleshoot 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.

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

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 1-877-406-6835 or the FDA at 1-800-FDA-1088 or at http://www.fda.gov/medwatch.

Contact Information For The IONSYS REMS Program


For additional information about the IONSYS REMS Program, please call 877-488-6835.
**24. Education Page 6**

**Instructions for Use and Disposal**

**IONSYS®**

fentanyl iontophoretic transdermal system, 40mcg/activation

For single use only. Up to 24 hours or 60 doses, whichever comes first.

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

- IONSYS Medication Guide
- IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists

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Reference ID: 4329753
25. Education Page 7

Instructions for Use and Disposal (continued)

1. Prepare Patient Site

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

Fig. 1a
26. Education Page 8

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.
27. Education Page 9

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 Medication Guide to counsel your patient on the safe use of IONSYS.
28. Education Page 10

Instructions for Use and Disposal (continued)

4. Apply IONSYS to Patient:
   ▶ Always wear gloves when handling IONSYS.
   a. Peel off clear liner and apply IONSYS to the prepared site (see Figure 4a).
   b. Press and hold IONSYS onto patient for 15 seconds by pressing the edges
      with fingers (see Figure 4a). Do not press dosing button.
   c. If IONSYS is not securely adhered, see IONSYS Troubleshooting — Poor
      skin contact.

   NOTE: Ensure proper display orientation by rotating "Doses Delivered" printed
   below the digital display.
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).
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.
  a. With gloves on, remove IONSYS from the patient (see Figure 6a).
  b. Pull the red tab to separate the red housing containing the drug (see Figure 6b).
  c. Fold the red housing in half and dispose per your institution's procedures or flush down the toilet (see Figure 6c).
  d. Hold down dosing button until display goes blank and dispose in waste designated for batteries.

![Instructions for Use and Disposal](image-url)
31. Education Page 13

Instructions for Use and Disposal (continued)

IONSYS Troubleshooting

After successful assembly or anytime during use:

If you see or hear this...

...then do this:

Blinking red for 15 seconds
Beeping for 15 seconds
Steady number
IONSYS is not securely adhered

Tape around long edges

Poor Skin Contact
a. 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.
b. If using tape, apply it along the long edges to secure IONSYS to patient’s skin.

Do not cover the button or display.
c. After taping, if IONSYS beeps again, remove and dispose. Place a new IONSYS on a different skin site.
d. Do not tape if evidence of blistered or broken skin.

No light
No beeps
Blank display

Low Battery or Defective System
a. Do not use the system.
b. Dispose of IONSYS per instructions in section 5.
c. Place a new IONSYS on a different skin site.

Blinking red
Beeping continuously
Steady number

System Error
a. Remove from patient.
b. Hold down dosing button until beeping stops and display goes blank.
c. Dispose of IONSYS per instructions in section 6.
d. Place a new IONSYS on a different skin site.

No light
No beeps
Blinking number

End-of-Use (60 doses or 24 hours)
a. Remove from patient.
b. Hold down dosing button until display goes blank.
c. Dispose of IONSYS per instructions in section 6.
d. Place a new IONSYS on a different skin site.
32. Knowledge Assessment Landing Page

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 IONSYS REMS Program you will need to answer all questions correctly. Please select the best option for each question.

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.

33. Knowledge Assessment #1

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
34. Knowledge Assessment #2

Knowledge Assessment

Question 2

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

- A. True
- B. False

Next

35. Knowledge Assessment #3

Knowledge Assessment

Question 3

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

- A. True
- B. False

Next
36. Knowledge Assessment #4

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

37. Knowledge Assessment #5

Knowledge Assessment

Question 5
The IONSYS Medication Guide 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 from 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 Medication Guide can only be obtained from hospital pharmacies

Next
38. Knowledge Assessment #6

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

39. Knowledge Assessment #7

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

Next
40. Knowledge Assessment #8

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

Next

41. Knowledge Assessment #9

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
42. Knowledge Assessment – Success Page for Hospital

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-S99P

**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
43. Knowledge Assessment – Success Page for Nurses and Pharmacists

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 will also receive an email confirmation if your method of contact is applicable.

If you affiliated with a certified hospital, your successful completion of the training and Knowledge Assessment will be automatically uploaded to your Hospital Authorized Representative's online dashboard along with their receiving confirmation by email if applicable.

Knowledge Assessment Code: 1646-H454-P545

For additional information about the IONSYS REMS Program, please call 877-488-6835.
44. 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.
45. Knowledge Assessment – Failed 3rd 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.

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.

- D. False
46. Knowledge Assessment – Failed 6th 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.

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.
47. Hospital Attestation

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 the 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 Medication Guide 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 Medication Guide 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 will ensure that the certified hospital involved in the prescribing, dispensing, and administration of IONSYS are informed of rates 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.
8. I understand that the hospital pharmacy is not to dispense IONSYS for use outside the hospital.
9. I understand that IONSYS must be removed from the patient prior to the patient leaving the hospital.
10. 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.
11. 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.
12. I will renew this hospital’s certification in the IONSYS REMS Program every 3 years after initial certification.
13. I understand that hospital must have a new Authorized Representative complete an IONSYS REMS Hospital Enrollment Form and successfully complete the IONSYS REMS Knowledge Assessment within 3 weeks of the hospital designating a new Authorized Representative.

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

Signature: [signature]
Signature Date: [date]

For additional information about the IONSYS REMS Program, please call 877-488-6835.
48. My Dashboard – View Hospitals

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.

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>Certification ID</th>
<th>Certification Status</th>
<th>Certified Date</th>
<th>Expiration Date</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health &amp; Hospital Corp of Maricopa Co</td>
<td>15 Park Avenue, New York, NY 10001</td>
<td>FAC849482209</td>
<td>Certified</td>
<td>03/15/2015</td>
<td>03/15/2015</td>
<td>View</td>
</tr>
<tr>
<td>Floyd Valley Hospital</td>
<td>600 Main Street, Phoenix, AZ 85017</td>
<td>FAC849484848</td>
<td>incomplete</td>
<td></td>
<td></td>
<td>Re-certify</td>
</tr>
<tr>
<td>Western State Hospital</td>
<td>23477th Street, Los Angeles, CA 90037</td>
<td>FAC845866556</td>
<td>Deactivated</td>
<td>03/15/2015</td>
<td>07/27/2015</td>
<td></td>
</tr>
</tbody>
</table>

1 - 3 of 3 Items

Add Hospital
49. My Dashboard – View Nurses and Pharmacists

Welcome to your IONSYS REMS Program dashboard.

Below are the nurses and pharmacists associated with your Hospital location(s) along with their Knowledge Assessment status.

<table>
<thead>
<tr>
<th>Name</th>
<th>Hospital Name</th>
<th>Hospital Address</th>
<th>Knowledge Assessment Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>John Doe</td>
<td>Health &amp; Hospital Corp of Marion Co</td>
<td>15 Park Avenue, New York NY 10021</td>
<td>Complete</td>
</tr>
<tr>
<td>John Smith</td>
<td>Floyd Valley Hospital</td>
<td>800 Main Street, Phoenix AZ 84747</td>
<td>Incomplete</td>
</tr>
</tbody>
</table>

1 - 2 of 2 items
50. Hospital Certification Progress – Certified

Health & Hospital Corp of Marion Co

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

<table>
<thead>
<tr>
<th>Activity</th>
<th>Progress</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Account Registration</td>
<td>✔ Completed</td>
<td></td>
</tr>
<tr>
<td>Enrollment Form</td>
<td>✔ Completed</td>
<td></td>
</tr>
<tr>
<td>Education Resources</td>
<td>✔ Completed</td>
<td>Download Education Resources</td>
</tr>
<tr>
<td>Knowledge Assessment</td>
<td>✔ Completed</td>
<td></td>
</tr>
<tr>
<td>Certification Attestation</td>
<td>✔ Completed</td>
<td>Print Confirmation</td>
</tr>
<tr>
<td>My Profile</td>
<td>✔ Available</td>
<td>View</td>
</tr>
</tbody>
</table>

51. Hospital Certification Progress – Incomplete Certification

Floyd Valley Hospital

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

<table>
<thead>
<tr>
<th>Activity</th>
<th>Progress</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Account Registration</td>
<td>✔ Completed</td>
<td></td>
</tr>
<tr>
<td>Enrollment Form</td>
<td>incomplete</td>
<td>Edit Enrollment Form</td>
</tr>
<tr>
<td>Education Resources</td>
<td>incomplete</td>
<td>Start Education Program</td>
</tr>
<tr>
<td>Knowledge Assessment</td>
<td>incomplete</td>
<td></td>
</tr>
<tr>
<td>Certification Attestation</td>
<td>incomplete</td>
<td></td>
</tr>
<tr>
<td>My Profile</td>
<td>✔ Available</td>
<td>View</td>
</tr>
</tbody>
</table>
52. Nurses and Pharmacists Progress – KA Incomplete

Frank Adam

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

<table>
<thead>
<tr>
<th>Activity</th>
<th>Progress</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Account Registration</td>
<td>Completed</td>
<td></td>
</tr>
<tr>
<td>Education Resources</td>
<td>Incomplete</td>
<td>Start Education Program</td>
</tr>
<tr>
<td>Knowledge Assessment</td>
<td>Incomplete</td>
<td></td>
</tr>
</tbody>
</table>

53. Nurses and Pharmacists Progress – KA Completed

Frank Adam

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

<table>
<thead>
<tr>
<th>Activity</th>
<th>Progress</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Account Registration</td>
<td>Completed</td>
<td></td>
</tr>
<tr>
<td>Education Resources</td>
<td>Completed</td>
<td>Download Education Resources</td>
</tr>
<tr>
<td>Knowledge Assessment</td>
<td>Completed</td>
<td>Print Confirmation</td>
</tr>
</tbody>
</table>
54. Hospital 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: FAC84747474

You may now:
- Manage your hospitals
- View your profile
55. Authorized Representative Profile

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 877-489-5635. 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  Nurse
Phone  898-938-3464
Ext  8558
Fax  585-383-3838
Email  <email address>
Preferred Method of Communication  Email
56. Forms & Resources

Forms & Resources

Forms

IONSYS® 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® Medication Guide
Prescribing Information
57. 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
Last Name
Email Address

Submit
58. 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.

![Request Password Form]

59. 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.

![Change Password Form]
60. Contact Us

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 26242
PHOENIX, AZ 85038-9242
61. Certification Deactivated Message – Program Opt Out, Hospital Closed, AR Not Confirmed, Expired – My Dashboard

![Certification Deactivated]

Based on the information provided, we have determined that your certification was deactivated for the following reason: AR Not Confirmed.

If you wish to begin the re-certification process, please click on the Start Re-Certification button or use the My Dashboard button to stay on your My Dashboard page.

Please contact the IONSYS REMS Program at 877-488-6835 if you need any further assistance.

My Dashboard

62. Certification Cancelled Message – 6-Month Incomplete Certification – My Dashboard

![Certification Cancelled]

Based on the information provided, we have determined that your certification was cancelled for the following reason: 6-month Incomplete Certification. Please click the OK button to start your certification.

Please contact the IONSYS REMS Program at 877-488-6835 for further assistance.

OK
63. Certification Cancelled Message – Suspension, Non Compliant – My Dashboard

64. Identifier Validation Message – DEA #/Identifier Could Not Be Validated – Hospital and AR Website Certification
65. **Identifier Validation Message – May Already Be Certified – Hospital and AR Website Certification**

![Identifier Validation Message](image)

66. **User ID Already Exists – Website Certification**

The User Id already exists.

- **First Name**
- **Last Name**
- **Email Address**
- **Certification ID** (Optional)
- **Username**
- **Password**
- **Confirm Password**

**Submit**
This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JUDITH A RACOOSIN
10/03/2018