IONSYS®
(Transdermal System)

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 20242, Phoenix, AZ 85038-0242. 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 the implementation and compliance with the IONSYS REMS Program.
2. I attest that this hospital provides acute care, treats patients in the hospital, and offers post-operative pain management.
3. I have reviewed the IONSYS Prescribing Information, IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists (to which the IONSYS Instructions for Use and Disposal and the IONSYS Guide for Patients are attached), and I have successfully completed the IONSYS REMS Knowledge Assessment.
4. I understand the benefits and risks associated with IONSYS and the requirements of the IONSYS REMS Program.
5. I will ensure all staff, including pharmacy and nursing staff, involved in dispensing or administering IONSYS have been trained on the IONSYS REMS Program requirements as described in the IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists (to which the IONSYS Instructions for Use and Disposal and the IONSYS Guide for Patients are attached) and have successfully completed the IONSYS REMS Knowledge Assessment. This training will be documented.
6. I will establish or oversee the processes, procedures, systems, order sets, protocols, and/or other measures to help ensure compliance with the requirements of the IONSYS REMS Program. These processes, procedures, and/or other measures will be documented.
7. I understand that the hospital will 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 the 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.
### IONSYS® REMS HOSPITAL ENROLLMENT FORM

All Fields Required Unless Otherwise Indicated.

<table>
<thead>
<tr>
<th>Authorized Representative Signature:</th>
<th>Date:</th>
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</thead>
<tbody>
<tr>
<td>Authorized Representative Printed Name (First, Last):</td>
<td>Title:</td>
</tr>
</tbody>
</table>

If State License Number is provided, License State and State License Type fields are required.

<table>
<thead>
<tr>
<th>Authorized Representative State License Number (optional):</th>
<th>License State:</th>
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</thead>
<tbody>
<tr>
<td>State License Type: MD □ DO □ PA □ RN □ NP □ RPh □ PharmD □ Other:</td>
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**Name of Hospital:**

<table>
<thead>
<tr>
<th>Hospital Pharmacy Street Address:</th>
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<tbody>
<tr>
<td>City:</td>
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<tr>
<td>State Hospital License Number:</td>
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<tr>
<th>Phone Number:</th>
<th>Fax Number:</th>
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**Email Address:**

Preferred Method of Communication (Please choose one): Email □ Fax

**Hospital Pharmacy DEA License Number:**

**Hospital Pharmacy DEA License Number Expiration Date (optional):**

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

The Medicines Company

This form is part of an FDA-approved REMS.

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