TIRF REMS ACCESS

Transmucosal Immediate Release Fentanyl (TIRF) REMS Access Program

Patient-Prescriber Agreement Form

For real-time processing of this enrollment form electronically, please go to **www.TIRFREMSaccess.com** and 'Log In' (if you have previously enrolled in a REMS program for one of the TIRF medicines) or 'Create an Account' to get started.

To submit this form via fax, please complete all required fields below and fax all pages to 1-866-822-1487.

As the prescriber of any TIRF medicine in this TIRF REMS (Risk Evaluation and Mitigation Strategy) Access program, I acknowledge that:

1. My patient is currently using around-the-clock opioid medication and has been for at least one (1) week.

2. My patient is opioid-tolerant. Patients considered opioid-tolerant are those who are regularly taking at least: 60 mg oral morphine/day; 25 micrograms transdermal fentanyl/hour; 30 mg oral oxycodone/day; 8 mg oral hydromorphone/day; 25 mg oral oxymorphone/day; or an equianalgesic dose of another opioid for one week or longer.

3. I have provided to, and reviewed with, my patient or their caregiver the Medication Guide for the TIRF medicine I intend to prescribe.

4. If I change my patient to a different TIRF medicine, I will provide the Medication Guide for the new TIRF medicine to my patient or my patient's caregiver, and I will review it with them.

5. I understand that if I change my patient to a different TIRF medicine, the initial dose of that TIRF medicine for all patients is the lowest dose, unless individual product labels provide product-specific conversion recommendations.

6. I have counseled my patient or their caregiver about the risks, benefits, and appropriate use of the TIRF medicine including communication of the following safety messages:

- **a.** If you stop taking your around-the-clock pain medicine, you must stop taking your TIRF medicine.
- **b.** NEVER share your TIRF medicine.
- **c.** Giving a TIRF medicine to someone for whom it has not been prescribed can result in a fatal overdose.
- **d.** TIRF medicines can be fatal to a child; used and unused dosage units must be safely stored out of the reach of children living in or likely to visit the home and disposed of in accordance with the specific disposal instructions detailed in the product's Medication Guide.

Prescriber (*Required Fields):

Signature* _____ Date ___/___/___

First and Last Name* (please print) _____

DEA Number* _____ National Provider Identifier (NPI)* _____

Fax* _____

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Prescriber Name* (please print): _____

For more information about TIRF medicines, please see Full Prescribing Information, including BOXED WARNINGS

Patient-Prescriber Agreement Form

As the patient being prescribed a TIRF medicine, or a legally authorized representative, I acknowledge that:

1. My prescriber has given me a copy of the Medication Guide for the TIRF medicine I have been prescribed, and has reviewed it with me.
2. I understand that before I can take any TIRF medicine, I must be regularly using another opioid pain medicine, around-the-clock, for my constant pain.
3. I understand that if I stop taking my around-the-clock opioid pain medicine for my constant pain, I must stop taking my TIRF medicine.
4. I understand how I should take this TIRF medicine, including how much I can take, and how often I can take it. If my prescriber prescribes a different TIRF medicine for me, I will ensure I understand how to take the new TIRF medicine.
5. I understand that any TIRF medicine can cause serious side effects, including life-threatening breathing problems which can lead to death, especially if I do not take my TIRF medicine exactly as my prescriber has directed me.
6. I agree to contact my prescriber if my TIRF medicine does not relieve my pain. I will not change the dose of my TIRF medicine myself or take it more often than my prescriber has directed.
7. I agree that I will never give my TIRF medicine to anyone else, even if they have the same symptoms, since it may harm them or even cause death.
8. I will store my TIRF medicine in a safe place away from children and teenagers because accidental use by a child, or anyone for whom it was not prescribed, is a medical emergency and can cause death.
9. I have been instructed on how to properly dispose of my partially used or unneeded TIRF medicine remaining from my prescription, and will dispose of my TIRF medicine properly as soon as I no longer need it.
10. I understand that selling or giving away my TIRF medicine is against the law.
11. I have asked my prescriber all the questions I have about my TIRF medicine. If I have any additional questions or concerns in the future about my treatment with my TIRF medicine, I will contact my prescriber.
12. I have reviewed the 'Patient Privacy Notice for the TIRF REMS Access Program' below and I agree to its terms and conditions which allow my healthcare providers to share my health information, as defined in this document to the makers of TIRF medicines (TIRF Sponsors) and their agents and contractors, for the limited purpose of managing the TIRF REMS Access program.

Patient (*Required Fields)

Signature* _____ Date* ___/___/___

First and Last Name* (please print) _____ Phone Number* _____

Birthday (Month/Day/Year)* ☐☐/☐☐/☐☐☐☐ State* _____ Zip code (5 digits)* _____

Patient Representative (if required)

Signature* _____ Date* ___/___/___

First and Last Name* (please print) _____

Relationship to patient*: _____

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Prescriber Name* (please print): _____

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Patient-Prescriber Agreement Form

Patient Privacy Notice for the TIRF REMS Access Program—For the purpose of the TIRF REMS Access program, my name, address, telephone number and prescription information make up my 'Health Information.' My doctors, pharmacists, and healthcare providers may share my Health Information with the TIRF REMS Access program, and contractors that manage the TIRF REMS Access program. My Health Information will be kept in a secure database, and may only be used as stated below.

I allow the TIRF REMS Access program to receive, use, and share my Health Information in order to:

I. Enroll me in the TIRF REMS Access program and manage my participation (including contacting me) in the TIRF REMS Access program.

II. Provide me with educational information about the TIRF REMS Access program.

III. Contact my healthcare providers to collect my Health Information for the TIRF REMS Access program.

IV. I allow the TIRF REMS Access program to receive, use, and share my Health Information, using a unique, encrypted identifier instead of my name, in order to evaluate the proper use of TIRF medicines and the effectiveness of the TIRF REMS Access program.

V. Report to the FDA, about side effects from TIRF medicines and the TIRF REMS Access program effectiveness.

I understand that I am not required to sign this written approval. However, if I do not sign, I will not be able to enroll in the TIRF REMS Access program and will not be able to receive TIRF medicines.

I understand that I may withdraw this written approval at any time by faxing a signed, written request to the TIRF REMS Access program at 1-866-822-1487. Upon receipt of this written request, the TIRF REMS Access program will notify my healthcare providers about my request. My healthcare providers will no longer be able to share my Health Information with the TIRF REMS Access program once they have received and processed that request. However, withdrawing this written approval will not affect the ability of the TIRF REMS Access program to use and share my Health Information that it has already received to the extent allowed by law. If I withdraw this written approval, I will no longer be able to participate in the TIRF REMS Access program and will no longer be able to receive TIRF medicines.

The sponsors of the TIRF REMS Access program agree to protect my information by using and sharing it only for the purposes described.

If you have any questions or require additional information or further copies of any TIRF REMS Access documents, please visit either www.TIRFREMSaccess.com, or call the TIRF REMS Access program at 1-866-822-1483.

Prescriber Name* (please print): _____

For more information about TIRF medicines, please see Full Prescribing Information, including BOXED WARNINGS