The Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS) Access Program or TIRF REMS Access Program

An Overview for Patients and Caregivers

What are TIRF medicines?

TIRF medicines are prescription medicines that contain the drug fentanyl. TIRF medicines are used to manage breakthrough pain in adults with cancer who are routinely taking other opioid (narcotic) pain medicines around-the-clock for cancer pain. Please refer to the list of currently approved TIRF products located on the TIRF REMS website at www.TIRFREMSaccess.com/TirfUI/ProductList.

What is the TIRF REMS Access Program?

A REMS, or Risk Evaluation and Mitigation Strategy, is a program to help manage known or potential serious risks of a medicine. Because TIRF medicines have a risk of misuse, abuse, addiction, and overdose, the Food and Drug Administration (FDA) has required that all TIRF medicines only be available through a restricted program called the TIRF REMS Access program. Healthcare professionals who prescribe your TIRF medicine, as well as pharmacies that fill your prescriptions for TIRF medicine, must be enrolled in the program.

Why is the TIRF REMS Access Program needed?

Your TIRF medicine contains fentanyl, which can cause life threatening breathing problems, which can lead to death. These life threatening breathing problems can occur if you take more TIRF medicine than your healthcare provider tells you to take, or if the TIRF medicine is taken by anyone other than you.

The TIRF REMS Access program provides training for prescribers and pharmacists to help them select patients for whom TIRF medicines are appropriate. The TIRF REMS Access program also helps your healthcare provider and pharmacist provide advice and guidance to you on the correct way to use your TIRF medicine, including how to store and dispose of it.

How do I participate in the program?

You or your caregiver will be required to read and sign the TIRF REMS Access Patient-Prescriber Agreement Form to participate in the program. Your healthcare provider will explain the Patient-Prescriber Agreement Form for the TIRF REMS Access program, which you must read and sign before receiving your prescription. Your healthcare provider will ensure that the signed form is submitted to the program. You will be part of the program when your first prescription is filled at a participating pharmacy. Your healthcare provider can identify pharmacies in your area where you can bring your prescription. When you are part of the program, you can start treatment with the TIRF medicine that your healthcare provider has prescribed for you.

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Overview of Steps for the TIRF REMS Access Program for Patients

Step 1
Participating in the Program

- Your healthcare provider will talk with you about the best way to use your TIRF medicine, including the risks and how to store and dispose of it correctly. Your healthcare provider will also review written information about your TIRF medicine with you. This written information is called the Medication Guide. Your healthcare provider will give you a copy of the Medication Guide - **read and keep it.**
- Together you and your healthcare provider will complete and sign the TIRF REMS Access Patient-Prescriber Agreement Form. The form gives you important information you need to know and understand before taking a TIRF medicine.
- You will need to complete a new Patient-Prescriber Agreement Form every two (2) years. You will be notified by your healthcare provider in advance of the need to re-enroll.
- Your healthcare provider will submit a copy to the TIRF REMS Access program.
- Your healthcare provider will also give you a copy and keep a copy in your medical records.

Step 2
Getting a Prescription

- Once you have signed the Patient-Prescriber Agreement Form your healthcare provider will write you a prescription for your TIRF medicine.
- Your healthcare provider can help you find a participating pharmacy to have your prescription filled, because only pharmacies that are in the TIRF REMS Access program can dispense TIRF medicines. You can also find a participating pharmacy by calling the TIRF REMS Access program at 1**-866-822-1483**.

Step 3
Having your Prescription Filled

- The pharmacy will check to make sure that your healthcare provider is enrolled in the TIRF REMS Access program. Only then is the pharmacy allowed to dispense the TIRF medicine to you.
- You will be automatically enrolled in the TIRF REMS Access program when **y**ou receive your first prescription for a TIRF medicine.
- The pharmacy will remind you how to take, store and dispose of your TIRF medicine correctly.
- The pharmacy will also give you a copy of the Medication Guide. Read and keep the Medication Guide.

Additional Program Information

For more information about your TIRF medicine, you can find a copy of the Medication Guide at www.TIRFREMSaccess.com or you can call the TIRF REMS Access program at **1-866-822-1483**.

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