

The Transmucosal Immediate Release Fentanyl (TIRF) REMS Access Program

Prescriber Enrollment Form

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For real-time processing of enrollment, please go to <u>www.TIRFREMSaccess.com</u>.

To submit this form via fax, please complete all required fields below and fax pages 1, 2, and 3 to **1-866-822-1487**. Please note, you must review the TIRF REMS Access Education Program and successfully complete the Knowledge Assessment to complete enrollment. If you have not completed the Knowledge Assessment online, please include it with this enrollment form. You will receive enrollment confirmation via email or fax.

I understand that TIRF medicines are only available through the TIRF REMS (Risk Evaluation and Mitigation Strategy) Access program and that I must comply with the program requirements. In addition, I acknowledge that:

- 1. I have reviewed the TIRF REMS Access Education Program, including the Full Prescribing Information for each TIRF medicine, and I have completed the Knowledge Assessment. I understand the responsible use conditions for TIRF medicines and the risks and benefits of chronic opioid therapy.
- 2. I understand that TIRF medicines can be abused and that this risk should be considered when prescribing or dispensing TIRF medicines in situations where I am concerned about an increased risk of misuse, abuse, or overdose, whether accidental or intentional.
- 3. I understand that TIRF medicines are indicated only for the management of breakthrough pain in cancer patients 18 years of age or older (Actiq and its generic equivalents are approved for 16 years of age and older), who are already receiving and who are tolerant to, around-the-clock opioid therapy for their underlying persistent cancer pain.
- **4.** I understand that TIRF medicines are contraindicated for use in opioid non-tolerant patients, and know that fatal overdose can occur at any dose.
- I understand that TIRF medicines must not be used to treat acute or postoperative pain, including headache/migraine, dental pain, or acute pain in the emergency department.
- 6. I understand that converting patients from one TIRF medicine to a different TIRF medicine must not be done on a microgram-per-microgram basis. I understand that TIRF medicines are not interchangeable with each other, regardless of route of administration, and that conversion may result in fatal overdose, unless conversion is done in accordance with labeled productspecific conversion recommendations (refer to the TIRF REMS Access website at www.TIRFREMSaccess. com/TirfUs/rems/products.action). Note, a branded

TIRF medicine and its specific generic product(s) are interchangeable.

- I understand that the initial starting dose for TIRF medicines for <u>all</u> patients is the lowest dose, unless individual product labels provide product-specific conversion recommendations, and I understand that patients must be titrated individually.
- 8. I will provide a Medication Guide for the TIRF medicine I intend to prescribe to my patient or their caregiver and review it with them. If I convert my patient to a different TIRF medicine, the Medication Guide for the new TIRF medicine will be provided to, and reviewed with my patient or their caregiver.
- 9. I will complete and sign a TIRF REMS Access Patient-Prescriber Agreement (PPAF) with <u>each</u> new patient before writing the patient's first prescription for a TIRF medicine and renew the agreement every two (2) years.
- 10. I will provide a completed, signed copy of the Patient-Prescriber Agreement (PPAF) to the patient and retain a copy for my records. I will also provide a completed, signed copy to the TIRF REMS Access program (through the TIRF REMS Access website or by fax) within ten (10) working days.
- 11. At all follow-up visits, I agree to assess the patient for appropriateness of the dose of the TIRF medicine, and for signs of misuse and abuse.
- 12. I understand that TIRF medicines are only available through the TIRF REMS Access program. I understand and agree to comply with the TIRF REMS Access program requirements for prescribers.
- I understand that I must re-enroll in the TIRF REMS Access program and successfully complete the enrollment requirements every two (2) years.

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Prescriber Name* (please print): _______ For more information about TIRF medicines, please see Full Prescribing Information, including BOXED WARNINGS.

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Prescriber Enrollment Form

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Prescriber Information (*Required Fields):

Prescriber Signature*		Date*	
First Name*	Last Name*	Credentials	
State License Number*	State Issued* DEA Number*	National Provider Identifier (NPI)*	
Site Name*			
Address*			
City*	State*	ZIP*	
Phone Number*	Fax Number*	Email*	

Preferred Method of Communication (please select one):

If you have additional practice sites, state licenses, or DEA numbers that you may use when prescribing TIRF medicines, please provide the information requested below.

Additional Prescriber Information (All Fields Required):

Site Name*				
Address*				
City*		State*	ZIP*	
Phone Number*	Fax Number*			
State License Number*	State Issued* DEA N			

Prescriber Name* (please print): ______ For more information about TIRF medicines, please see Full Prescribing Information, including BOXED WARNINGS.

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Prescriber Enrollment Form

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Additional Prescriber Information (All Fields Required):

Site Name*				
Address*				
City*		State*	ZIP*	
Phone Number*	Fax Number*			
State License Number*	State Issued* DEA N	umber*		
Site Name*				
Address*				
City*		State*	ZIP*	
Phone Number*	Fax Number*			
State License Number*	State Issued* DEA N	umber*		

If you have any questions or require additional information or further copies of any TIRF REMS Access documents, please visit either <u>www.TIRFREMSaccess.com</u> 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.