

The Transmucosal Immediate Release Fentanyl (TIRF) REMS Access Program

Prescriber Enrollment Form

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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 pages 1, 2, and 3 to 1-866-822-1487. 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:

- 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 patients with cancer, who are already receiving, and who are tolerant to, around-the-clock opioid therapy for their underlying persistent pain.
- **4.** I understand that TIRF medicines are contraindicated for use in opioid non-tolerant patients, and know that fatal overdose can occur.
- **5.** I understand that TIRF medicines must not be used to treat any contraindicated conditions described in the full Prescribing Information, such as acute or postoperative pain, including headache/migraine.
- 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 labelled product-specific conversion recommendations (refer to the 'List of the TIRF medicines Available only through the TIRF REMS Access program' in Attachment 1). Note, substitution between a branded TIRF medicine and its specific generic product(s) are interchangeable.

- 7. 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.
- **13.** 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 Information (*Required Fields):

		/ /	
Prescriber Signature*		Date*	
First and Last Name* (please p	Credentials		
State License Number*	State Issued* DEA Number*	National Provider Identifier (NPI)*	
Site Name*			
Address*			
City*	State*	ZIP*	
referred Method of Com	Fax Number* munication (please select one): Fax ctice sites, state licenses or DEA number the information requested below.	Email* □ Email s that you may use when prescribing	
you have additional prac nedicines, please provide	munication (please select one): Fax etice sites, state licenses or DEA number the information requested below.	□ Email	
referred Method of Com you have additional prac nedicines, please provide	munication (please select one): Fax etice sites, state licenses or DEA number	□ Email	
referred Method of Com you have additional practicedicines, please provide	munication (please select one): Fax etice sites, state licenses or DEA number the information requested below.	□ Email	
referred Method of Com you have additional prac edicines, please provide	munication (please select one): Fax etice sites, state licenses or DEA number the information requested below.	□ Email	
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referred Method of Com you have additional prace edicines, please provide dditional Prescriber Info	munication (please select one): Fax ctice sites, state licenses or DEA number the information requested below. prmation (All Fields Required):	□ Email Is that you may use when prescribing	

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Additional Prescriber Information (All Fields Required):

dutional Prescriber Information (All Fields Required).				
Site Name*				
Address*				
City*		ZIP*		
Phone Number*	Fax Number*			
State License Number*	State Issued* DEA Number*			
Site Name*				
Address*				
7.144.1.000				
City*	State*	ZIP*		
Phone Number*	Fax Number*			
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State License Number*	State Issued* DEA Number*	·		
State Electise National	State 133ded DEA Number			

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.



Attachment 1

List of TIRF medicines Available Only through the TIRF REMS Access program

- ABSTRAL® (fentanyl) sublingual tablets
- ACTIQ® (fentanyl citrate) oral transmucosal lozenge
- FENTORA® (fentanyl citrate) buccal tablet
- LAZANDA® (fentanyl) nasal spray
- **ONSOLIS**® (fentanyl buccal soluble film)
- **SUBSYS™** (fentanyl sublingual spray)
- Approved generic equivalents of these products are also covered under this program.