

On December 28, 2011, the U.S. Food and Drug Administration (FDA) approved a single, shared system Risk Evaluation and Mitigation Strategy (REMS) for the entire class of transmucosal immediate-release fentanyl (TIRF) products. The TIRF REMS Access program consists of a restricted distribution program to reduce the risk of misuse, abuse, addiction, and overdose with TIRF medicines. The TIRF REMS Access program is the first approved class REMS for drugs in the opioid class. TIRF products are indicated only to manage break-through cancer pain in adults who are opioid tolerant and routinely receiving additional opioid therapy for persistent cancer pain. The FDA is also currently working on another class REMS covering long-acting and extended-release opioids.

Currently Available Transmucosal Immediate-Release Fentanyl (TIRF) Products

Fentanyl Transmucosal Product	Dosage Form	Generic Available?
Abstral	Sublingual tablet	No
Actiq	Lozenge	Yes
Fentora	Buccal tablet	No
Lazanda	Intranasal spray	No
Onsolis	Buccal film	No

The shared system strategy, called the TIRF REMS Access Program, will be used by all sponsors of TIRF products and is expected to ease the burden on the health care system. The program will begin in March 2012. Until that time, prescribers, patients, and pharmacies should continue to enroll in the individual REMS programs. Prescribers and pharmacies already enrolled in an individual REMS program for at least one TIRF medicine will automatically be transitioned to the shared TIRF REMS Access program when available.

Health care professionals who prescribe TIRF medicines that will only be used in an inpatient setting (hospitals, hospices, or long-term care facilities) will not be required to enroll in the TIRF REMS Access program. Similarly, patients who receive TIRF medicines in an inpatient setting are not required to enroll in the program. **Long-term care and hospice patients who obtain their medications from outpatient pharmacies must still be enrolled.** In outpatient settings, all healthcare providers must complete and sign a TIRF REMS Access Patient-Prescriber Agreement Form with each new patient before writing the patient's first TIRF prescription. Healthcare providers must also provide patients with a copy of the Medication Guide during counseling about the proper use of their TIRF medicine.

The goals of the TIRF REMS Access Program are to ensure patient access to important medications and mitigate the risk of misuse, abuse, addiction, overdose and serious complications due to medication errors by:

- prescribing and dispensing TIRF medicines only to appropriate patients, including use only in opioid-tolerant patients
- preventing inappropriate conversion between fentanyl products
- preventing accidental exposure to children and others for whom TIRF medicines were not prescribed
- educating prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose

Additional information the new system is available via the TIRF REMS Access website at:
<http://www.tirfremaccess.com/>

References:

1. Food and Drug Administration (FDA). FDA approves shared system REMS for TIRF products. Accessed 1/5/2012. Available at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm285345.htm>