

## What You need to Know about Your TIRF Medicine

Read and keep this guide and the Medication Guide that was given to you by your pharmacy with your medicine.

Go over this information with your healthcare provider and ask about anything you do not understand.

### What are TIRF Medicines?

- A transmucosal immediate-release fentanyl (TIRF) medicine is a prescription medicine that contains fentanyl, a very strong opioid pain reliever.
- TIRF medicines are used to manage breakthrough cancer pain in patients who are already routinely taking another opioid pain medicine around-the-clock, for at least one week or longer.
- TIRF medicines are started only after you have been taking other opioid pain medicines and your body has become use to them (meaning you are opioid tolerant).
- **You must stop taking your TIRF medicine if you stop taking your around-the-clock opioid pain medicine.**



### What are the serious risks of using TIRF Medicines?

- Too much TIRF medicine in your body can cause your breathing to stop—which could lead to death.
- Accidental use of a TIRF medicine by a child, or anyone else can cause death.
- Avoid accidental exposure by storing your TIRF medicine in a place where it cannot be reached by children, and where it cannot be stolen by other family members or visitors to your home. Use a lockbox or locking medication bag to keep your TIRF medicine safe and secure.
- TIRF medicines, like other opioids, have serious risks of misuse, abuse and addiction that can lead to death.
- These serious risks can occur even when you use your TIRF medicine as recommended.

The risk of life-threatening breathing problems is greatest:

- if you are not opioid-tolerant
- when you start your TIRF medicine,
- when the dose is increased or
- when changing TIRF medicines

The risk is also greater for people taking other medicines that make them feel sleepy or people with sleep apnea.

### How can I take a TIRF Medicine Safely?

- Take your TIRF medicine exactly as your healthcare provider has directed.
- Call your healthcare provider if the TIRF medicine is not controlling your breakthrough cancer pain. Do not increase the dose on your own or take the TIRF medicine more frequently than was directed.

Unless prescribed by your healthcare provider, do not take any of the following with a TIRF medicine. The combination can cause severe drowsiness, confusion, breathing problems, coma and death.

- Alcohol, including any prescription or over-the-counter medicines containing alcohol
- Benzodiazepines, tranquilizers, and anti-anxiety medicines (like Valium or Xanax)
- Muscle relaxants (like Soma or Flexeril)
- Sleep medicines (like Ambien or Lunesta)

# Patient Counseling Guide



- Do not switch from your TIRF medicine to another medicine containing fentanyl without talking to your healthcare provider first.
- It is against the law to share your TIRF medicine or give it to anyone else even if they have the same symptoms.
- If you become aware that a child or anyone else takes your TIRF medicine, get emergency medical help immediately. These are medical emergencies that can cause death. A dose that is okay for you could cause an overdose and death in someone else.



## How can I dispose of my TIRF Medicine safely?

- When you no longer need your TIRF medicine, dispose of it properly and as quickly as possible.
- NEVER dispose of an unused TIRF medicine in an open trash bin where children, family or pets may accidentally come into contact with the TIRF medicine. Accidental exposure to a TIRF medicine by anyone who is not opioid tolerant is a medical emergency.



The Medication Guide received from your pharmacy with your TIRF medicine, tells the proper way to dispose of the unused portion of your TIRF medicine. Follow the disposal instructions provided in the Medication Guide exactly.

## What is Naloxone and When should I use it?

- Naloxone is a medicine that helps reverse an opioid overdose. It is sprayed inside your nose or injected into your body. Some naloxone products are designed for people to use in their home.
- If either of the following occurs, immediately use naloxone:
  - You or someone else has taken an opioid medicine, including a TIRF medicine, and is having trouble breathing, is short of breath, or is unusually sleepy
- A child has accidentally taken an opioid medicine, including a TIRF medicine, or you think they might have.
- Giving naloxone to a person, even a child, who has not taken an opioid medicine will not hurt them.
- Naloxone is never a substitute for emergency medical care. Always call 911 and go to the emergency room if the patient or someone else has used or been given naloxone. This is because they may have had an opioid overdose.
- Ask your healthcare provider how you can get naloxone. Naloxone is available in pharmacies, and in some states, you may not need a prescription.
- Keep naloxone in a place where you, your family, or friends can quickly get to it in an emergency.

# Patient Counseling Guide



## What should I know about the specific TIRF Medicine I am taking?

- Read the Medication Guide that comes with your TIRF medicine prescription for specific information about your medicine.
- You or your healthcare provider can write notes below about things you should know about your TIRF medicine. (This might include dosing instructions, other medicines that you should avoid when taking your specific TIRF medicine, or anything else that you or your healthcare provider want to write down.)

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## What if I have more questions?

- Talk to your healthcare provider or pharmacist and ask them any questions you may have.
- Visit [www.fda.gov/opioids](http://www.fda.gov/opioids) for more information about opioid medicines.

For information about the TIRF REMS call 1-866-822-1453 or visit [www.TIRFREMSAccess.com](http://www.TIRFREMSAccess.com)

