

## Medication Guide

### Fentanyl Transdermal System, CII

(fen' ta nil)

#### Fentanyl transdermal system is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage pain severe enough to require daily around-the-clock, long-term treatment with an opioid, in people who are already regularly using opioid pain medicine, when other pain treatments such as non-opioid pain medicines or immediate-release opioid medicines do not treat your pain well enough or you cannot tolerate them.
- A long-acting (extended-release) opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.
- Not for use to treat pain that is not around-the-clock.

#### Important information about fentanyl transdermal system:

- **Get emergency help right away if you use too much fentanyl transdermal system (overdose).** When you first start taking fentanyl transdermal system, when your dose is changed, or if you take too much (overdose), serious or life threatening breathing problems that can lead to death may occur.
- Never give anyone else your fentanyl transdermal system. They could die from using it. Store fentanyl transdermal system away from children and in a safe place to prevent stealing or abuse. Selling or giving away fentanyl transdermal system is against the law.
- If the patch accidentally sticks to a family member while in close contact, take the patch off, wash the area with water, and get emergency help right away because an accidental exposure to fentanyl transdermal system can lead to death or other serious medical problems.
- Proper disposal of fentanyl transdermal system after use and for unused patches when no longer needed: Fold the sticky sides of the patch together and flush down the toilet. Do not put patches in a trash can.

Do not use fentanyl transdermal system if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.

**Before applying fentanyl transdermal system, tell your healthcare provider if you have a history of:**

- head injury, seizures
- liver, kidney, thyroid problems
- problems urinating
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, or mental health problems.

**Tell your healthcare provider if you:**

- have a fever
- **are pregnant or planning to become pregnant.** Prolonged use of fentanyl transdermal system during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.

- **are breastfeeding.** Fentanyl transdermal system passes into breast milk and may harm your baby.
- are taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking fentanyl transdermal system with certain other medicines can cause serious side effects that could lead to death.

**When using fentanyl transdermal system:**

- Do not change your dose. Apply fentanyl transdermal system exactly as prescribed by your healthcare provider.
- See the detailed Instructions for Use for information about how to apply and dispose of the fentanyl transdermal system patch.
- Do not apply more than 1 patch at the same time unless your healthcare provider tells you to.
- You should wear the fentanyl transdermal patch continuously for 3 days, unless advised otherwise by your healthcare provider.
- **Call your healthcare provider if the dose you are using does not control your pain.**
- **Do not stop using fentanyl transdermal system without talking to your healthcare provider.**

**While using fentanyl transdermal system DO NOT:**

- Take hot baths or sunbathe, use hot tubs, saunas, heating pads, electric blankets, heated waterbeds, or tanning lamps, or engage in exercise that increases your body temperature. These can cause an overdose that can lead to death.
- Drive or operate heavy machinery, until you know how fentanyl transdermal system affects you. Fentanyl transdermal system can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol. Using products containing alcohol during treatment with fentanyl transdermal system may cause you to overdose and die.
- Wear this fentanyl transdermal system during any magnetic resonance imaging (MRI) procedures to avoid possible burns.

**The possible side effects of fentanyl transdermal system are:**

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain, itching, redness, or rash where the patch is applied. Call your healthcare provider if you have any of these symptoms and they are severe.

**Get emergency medical help if you have:**

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue or throat, extreme drowsiness, light-headedness when changing positions, or you are feeling faint.

These are not all the possible side effects of fentanyl transdermal system. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to [dailymed.nlm.nih.gov](http://dailymed.nlm.nih.gov)**

Manufactured by:

Aveva Drug Delivery Systems, Inc., Miramar, FL 33025;

Manufactured for:

Apotex Corp., Weston, FL 33326, [drugsafety@apotex.com](mailto:drugsafety@apotex.com) or call

1-888-333-6127, 9 A.M. to 5 P.M., Eastern Time, Monday through Friday.

This Medication Guide has been approved by the U.S. FDA.

Issue: May 2014