

**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 or call 911 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. Talk to your healthcare provider about naloxone, a medicine for the emergency treatment of an opioid overdose.
- Taking fentanyl transdermal system with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) may cause severe drowsiness, decreased awareness, breathing difficulties, with slow or shallow breathing, coma, and death.
- Never give anyone else your fentanyl transdermal system. They could die from taking it. Selling or giving away fentanyl transdermal system is against the law.
- Store fentanyl transdermal system, securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.
- 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.
- Dispose of expired, unwanted, or unused fentanyl transdermal system, by folding the patch so that the adhesive side of the patch adheres to itself, and immediately flushing down the toilet (if a drug take-back option is not readily available) [see *Instructions for Use*]. Visit [www.fda.gov/drugdisposal](http://www.fda.gov/drugdisposal) for additional information on disposal of unused medicines.

**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
- problems urinating
- liver, kidney, thyroid problems
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, opioid overdose, 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.** Not recommended during treatment with fentanyl transdermal system. It may harm your baby.
- are living in a household where there are small children or someone who has abused street or prescription drugs.
- are taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking fentanyl 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. Use the lowest dose possible for the shortest time needed.
- 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.
- Do not cut, break, chew, crush, dissolve, snort, or inject fentanyl transdermal system because this may cause you to overdose and die.
- **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.

**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 or call 911 right away 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, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, or mental changes such as confusion.

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. Food and Drug Administration.

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