

Medication Guide

DURAGESIC® (Dur-ah-GEE-zik) (fentanyl) Transdermal System, CII

DURAGESIC® 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 DURAGESIC®:

- **Get emergency help or call 911 right away if you use too much DURAGESIC® (overdose).** When you first start taking DURAGESIC®, 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 DURAGESIC® 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 DURAGESIC®. They could die from taking it. Selling or giving away DURAGESIC® is against the law.
- Store DURAGESIC®, 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 DURAGESIC® can lead to death or other serious medical problems.
- Dispose of expired, unwanted, or unused DURAGESIC®, 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 for additional information on disposal of unused medicines.

Do not use DURAGESIC® if you have:

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

Before applying DURAGESIC®, 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, 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 DURAGESIC® 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 DURAGESIC. 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 DURAGESIC® with certain other medicines can cause serious side effects that could lead to death.

When using DURAGESIC®:

- Do not change your dose. Apply DURAGESIC® 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 DURAGESIC® patch.
- Do not apply more than 1 patch at the same time unless your healthcare provider tells you to.
- You should wear the DURAGESIC® patch continuously for 3 days, unless advised otherwise by your healthcare provider.
- Do not cut, break, chew, crush, dissolve, snort, or inject DURAGESIC 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 DURAGESIC® without talking to your healthcare provider.**

While using DURAGESIC® 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 DURAGESIC® affects you. DURAGESIC® 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 DURAGESIC® may cause you to overdose and die.

The possible side effects of DURAGESIC® 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 DURAGESIC®. 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**

Manufactured by: Alza Corporation, Vacaville, CA 95688; Manufactured for: Janssen Pharmaceuticals, Inc. Titusville, NJ 08560, www.Duragesic.com or call 1-800-526-7736