

Medication Guide

OPANA® ER (Ō-pan-a) (oxymorphone hydrochloride) extended-release tablets, for oral use, CII

OPANA ER 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, 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 OPANA ER:

- **Get emergency help right away if you take too much OPANA ER (overdose).** When you first start taking OPANA ER, 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.
- Taking OPANA ER with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.
- Never give anyone your OPANA ER. They could die from taking it. Store OPANA ER away from children and in a safe place to prevent stealing or abuse. Selling or giving away OPANA ER is against the law.

Do not take OPANA ER if you have:

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

Before taking OPANA ER, 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 are:

- **pregnant or planning to become pregnant.** Prolonged use of OPANA ER during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **breastfeeding.** Not recommended during treatment with OPANA ER. It may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking OPANA ER with certain other medicines can cause serious side effects that could lead to death.

When taking OPANA ER:

- Do not change your dose. Take OPANA ER exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- Take your prescribed dose every 12 hours at the same time every day on an empty stomach, at least 1 hour before or 2 hours after meals. Do not take more than your prescribed dose in 24 hours. If you miss a dose, take your next dose at your usual time.
- Swallow OPANA ER whole. Do not cut, break, chew, crush, dissolve, snort, or inject OPANA ER because this may cause you to overdose and die.
- To avoid choking on the tablet OPANA ER should be taken 1 tablet at a time. Do not pre-soak, lick, or wet the tablet before placing in your mouth.
- **Call your healthcare provider if the dose you are taking does not control your pain.**
- **Do not stop taking OPANA ER without talking to your healthcare provider.**
- After you stop taking OPANA ER, flush any unused tablets down the toilet.

While taking OPANA ER DO NOT:

- Drive or operate heavy machinery, until you know how OPANA ER affects you. OPANA ER 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 OPANA ER may cause you to overdose and die.

The possible side effects of OPANA ER:

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. 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, or hands, hives, itching, rash, 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 OPANA ER. 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**

Distributed by: Endo Pharmaceuticals Inc., Malvern, PA 19355, www.endo.com or call 1-800-462-3636

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

Revised: December 2016

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