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 treat moderate to severe around-the-clock pain.

Important information about OPANA ER:

- Get emergency help right away if you take too much OPANA ER (overdose). OPANA ER overdose can cause life threatening breathing problems that can lead to death.
- Never give anyone else 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. OPANA ER may harm your unborn baby.
- breastfeeding. OPANA ER may pass into breast milk and may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements.

When taking OPANA ER:

- Do not change your dose. Take OPANA ER exactly as prescribed by your healthcare provider.
- 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 the missed dose as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule.
- Swallow OPANA ER whole. Do not cut, break, chew, crush, dissolve, or inject OPANA ER.
- 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.

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, extreme drowsiness, or you are feeling faint.

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

Manufactured for: Endo Pharmaceuticals Inc, Chadds Ford, PA 19317, www.endo.com or call 1-800-462-3636 OPANA® is a registered trademark of Endo Pharmaceuticals Inc.

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