

Medication Guide

TARGINIQ™ ER (tar-gih-NEEK E-R)

(oxycodone hydrochloride and naloxone hydrochloride extended-release tablets), CII

TARGINIQ 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 TARGINIQ ER:

- **Get emergency help right away if you take too much TARGINIQ ER (overdose).** When you first start taking TARGINIQ 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.
- Never give anyone else your TARGINIQ ER. They could die from taking it. Store TARGINIQ ER away from children and in a safe place to prevent stealing or abuse. Selling or giving away TARGINIQ ER is against the law.

Do not take TARGINIQ 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 TARGINIQ ER, tell your healthcare provider if you have a history of:

- head injury, seizures
- problems urinating
- liver, kidney, thyroid or heart problems
- 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 TARGINIQ ER during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **breastfeeding.** TARGINIQ ER passes into breast milk and may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking TARGINIQ ER with certain other medicines can cause serious side effects that could lead to death.

When taking TARGINIQ ER:

- Do not change your dose. Take TARGINIQ ER exactly as prescribed by your healthcare provider.
- Take your prescribed dose every 12 hours at the same time every day. Do not take more than your prescribed dose in 12 hours. If you miss a dose, take your next dose at your usual time.
- Swallow TARGINIQ ER whole. Do not cut, break, chew, crush, dissolve, snort, or inject TARGINIQ ER because this may cause you to overdose and die.
- **Call your healthcare provider if the dose you are taking does not control your pain.**
- **Do not stop taking TARGINIQ ER without talking to your healthcare provider.**
- After you stop taking TARGINIQ ER, flush any unused tablets down the toilet.

While taking TARGINIQ ER DO NOT:

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

The possible side effects of TARGINIQ ER are:

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain, anxiety, and sweating. 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, lightheadedness when changing positions, or you are feeling faint.

Call your healthcare provider if you get symptoms that may be related to opioid withdrawal including tremors, chills, diarrhea, irritability, and yawning.

These are not all the possible side effects of TARGINIQ 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 by: Purdue Pharma L.P., Stamford, CT 06901-3431, www.purduepharma.com or call 1-888-726-7535

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

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