

Medication Guide

TROXYCA® ER (TROKS' ih-ka ee' ahr)

(oxycodone hydrochloride and naltrexone hydrochloride) extended-release capsules, CII

TROXYCA 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 TROXYCA ER:

- **Get emergency help right away if you take too much TROXYCA ER (overdose).** When you first start taking TROXYCA 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 your TROXYCA ER. They could die from taking it. Store TROXYCA ER away from children and in a safe place to prevent stealing or abuse. Selling or giving away TROXYCA ER is against the law.

Do not take TROXYCA 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 TROXYCA 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 TROXYCA 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 TROXYCA ER. It may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking TROXYCA ER with certain other medicines can cause serious side effects that could lead to death.

When taking TROXYCA ER:

- Do not change your dose. Take TROXYCA 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. 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 TROXYCA ER whole. Do not cut, break, chew, crush, dissolve, snort, or inject TROXYCA ER because this may cause you to overdose and die.
- Do not give TROXYCA ER through a nasogastric tube or gastric tube (stomach tube).
- If you cannot swallow TROXYCA ER capsules, see the detailed Instructions for Use.
- **Call your healthcare provider if the dose you are taking does not control your pain.**
- **Do not stop taking TROXYCA ER without talking to your healthcare provider.**
- After you stop taking TROXYCA ER, flush any unused capsules down the toilet.

While taking TROXYCA ER DO NOT:

- Drive or operate heavy machinery until you know how TROXYCA ER affects you. TROXYCA ER can make you sleepy, dizzy, or lightheaded.
- Drink alcohol, or use prescription or over-the-counter medicines containing alcohol. Using products containing alcohol during treatment with TROXYCA ER may cause you to overdose and die.

The possible side effects of TROXYCA ER are:

- 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, 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 TROXYCA 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.**

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Instructions For Use
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(oxycodone hydrochloride and naltrexone hydrochloride) extended-release capsules, CII

- If you cannot swallow TROXYCA ER capsules whole, tell your healthcare provider. If your healthcare provider tells you that you can take TROXYCA ER by sprinkling the capsule contents on applesauce, follow these steps:

TROXYCA ER can be opened and the contents inside the capsule can be sprinkled on applesauce, as follows:

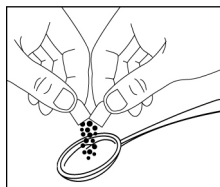


Figure 1

- Open the TROXYCA ER capsule and sprinkle the contents over about one tablespoon of applesauce (See Figure 1).

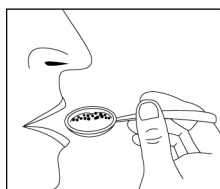


Figure 2

- Swallow all of the applesauce and sprinkled capsule contents right away. Do not save any of the applesauce and capsule contents for another dose (See Figure 2).

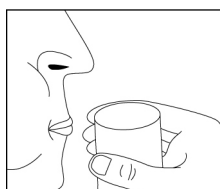


Figure 3

- Rinse your mouth to make sure you have swallowed all of the capsule contents. Do not chew the capsule contents (See Figure 3).

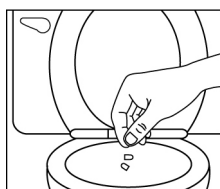


Figure 4

- Flush the empty capsule down the toilet right away (See Figure 4).

- Do not give TROXYCA ER through a nasogastric tube or gastric tube (stomach tube).

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