

Medication Guide

EXALGO® (eks-al-goh) (hydromorphone hydrochloride) extended-release tablets, CII

EXALGO 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 EXALGO:

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

Do not take EXALGO if you have:

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

Before taking EXALGO, tell your healthcare provider if you have a history of:

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

When taking EXALGO:

- Do not change your dose. Take EXALGO exactly as prescribed by your healthcare provider.
- Take your prescribed dose every 24 hours, at the same time every day. Do not take more than your prescribed dose in 24 hours. If you miss a dose, take your next dose at your usual time the next day.
- Swallow EXALGO whole. Do not cut, break, chew, crush, dissolve, snort, or inject EXALGO 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 EXALGO without talking to your healthcare provider.**
- EXALGO is contained in a hard tablet shell that you may see in your bowel movement; this is normal.
- After you stop taking EXALGO, flush any unused tablets down the toilet.

While taking EXALGO, DO NOT:

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

The possible side effects of EXALGO 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, or you are feeling faint.

These are not all the possible side effects of EXALGO. 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**

Trademarks are the property of a Mallinckrodt company.

Distributed by: Mallinckrodt Brand Pharmaceuticals, Inc., Hazelwood, MO 63042 USA, www.Exalgo.com or call 1-800-778-7898

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

Mallinckrodt™

Revised: April 2014