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 treat moderate to severe around-the-clock pain, in people who are already regularly using opioid pain medicine.

Important information about EXALGO:

- Get emergency help right away if you take too much EXALGO (overdose). EXALGO overdose can cause life threatening breathing problems that can lead to death.
- 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 hydromorphone or 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. EXALGO may harm your unborn baby.
- breastfeeding. EXALGO passes into breast milk and may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements.

When taking EXALGO:

- Do not change your dose. Take EXALGO exactly as prescribed by your healthcare provider.
- Take your prescribed dose at the same time every day. Do not take more than your prescribed dose in 24 hours. If
 you miss a dose, do not take EXALGO. Take your next dose at your usual time the next day.
- Swallow EXALGO whole. Do not cut, break, chew, crush, dissolve, or inject EXALGO.
- 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 that contain alcohol.

The possible side effects of EXALGO are:

• constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness. 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 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**

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