

Medication Guide

EXALGO™ (eks-al-goh) (hydromorphone hydrochloride) Extended Release Tablets, CII

IMPORTANT:

Keep EXALGO in a safe place away from children. Accidental use by a child is a medical emergency and can result in death. If a child accidentally takes EXALGO, get emergency help right away, even if the child is not having any side effects.

Read the Medication Guide that comes with EXALGO before you start taking it and each time you get a new prescription. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or your treatment. Share this important information with members of your household.

What is the most important information I should know about EXALGO?

1. EXALGO overdose can cause life threatening breathing problems that can lead to death.

- **Do not take** EXALGO unless you are already regularly using opioid pain medicines around-the-clock and your body is used to taking these medicines. **This means you are opioid tolerant.**
- **Take EXALGO exactly as prescribed by your healthcare provider. Do not take more than your prescribed daily dose. It is important that you do not take another dose of EXALGO within 24 hours.**
- **Swallow the EXALGO tablet whole. Do not break, chew, crush, or dissolve EXALGO before swallowing, or inject the contents.** You could receive the full daily dose of medicine too fast. This is very dangerous. It may cause you to have trouble breathing, and lead to death. If you cannot swallow EXALGO whole, tell your healthcare provider. You will need a different pain medicine.
- **EXALGO is not for use to treat pain that you only have once in a while ("as needed").**
- **EXALGO is not for use for short-term pain relief from injuries or surgery.**
- It is important for you to stay under the care of your healthcare provider while taking EXALGO.

2. Prevent theft, misuse, or abuse. Keep EXALGO in a safe place to protect it from being stolen. EXALGO can be a target for people who misuse or abuse prescription medicines or street drugs.

3. Never give EXALGO to anyone else, even if they have the same symptoms you have. It may harm them or cause death. Selling or giving away this medicine is against the law.

What is EXALGO?

- EXALGO is a prescription medicine that contains the opioid (narcotic) pain medicine hydromorphone. The medicine in EXALGO is slowly released over 24 hours. **If you break, chew, crush, or dissolve EXALGO before swallowing, or inject the contents, the hydromorphone hydrochloride may be released too fast and you may overdose.** See “What is the most important information I should know about EXALGO?”
- **EXALGO is a strong opioid pain medicine.** EXALGO is used in people who are opioid tolerant, to manage moderate to severe pain that continues around the clock and is expected to last for a long period of time.
- **EXALGO is a federally controlled substance (CII)** because it contains a strong opioid pain medicine that can be a target for people who abuse prescription medicines or street drugs.

Who should not take EXALGO?

Do not take EXALGO if you:

- are not already regularly taking opioid pain medicine and your body is not used to taking these medicines for your pain. This means you are not opioid tolerant.
- are having an asthma attack or have severe asthma, trouble breathing, or certain other lung problems
- have a bowel blockage called paralytic ileus
- have narrowing of the stomach or intestines, or have had surgery to your stomach or intestines
- are allergic to any of the ingredients in EXALGO or to medicines that contain sulfite. See the end of this Medication Guide for a complete list of the ingredients in EXALGO.

Talk to your healthcare provider before taking this medicine if you have any of the conditions listed above.

What should I tell my healthcare provider before starting EXALGO?

EXALGO may not be right for you. Before taking EXALGO, tell your healthcare provider if you:

- have trouble breathing or lung problems such as asthma, wheezing, or shortness of breath
- have had head injury or brain problem
- have liver or kidney problems
- **have an adrenal gland problem, such as Addison’s disease**
- have thyroid problems
- have seizures (convulsions or fits)
- have problems with your pancreas or gallbladder
- have constipation
- have had stomach or intestinal surgery, or a blockage in your stomach or intestine
- have prostate enlargement or problems urinating
- have low blood pressure
- have mental problems including depression, anxiety, or hallucinations (seeing or hearing things that are not there)
- have or had a drinking problem or alcoholism, or a family history of this problem

- have or had a drug abuse or addiction problem in the past, or a family history of this problem
- have any other medical conditions
- **are pregnant or planning to become pregnant.** If you take EXALGO regularly before your baby is born, your new born baby may have withdrawal symptoms because their body has become used to the medicine.

Symptoms of withdrawal in a newborn baby may include:

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| • irritability | • diarrhea or more stools than normal |
| • crying more than usual | • vomiting |
| • shaking (tremors) | • fever |
| • jitteriness | |
| • breathing faster than normal | |

If you take EXALGO right before your baby is born, your baby could have breathing problems.

- **Breast feeding.** Do not breastfeed while taking EXALGO. Some EXALGO passes into breast milk. A nursing baby could become drowsy or have difficulty breathing or feeding well. If you stop breast-feeding or suddenly stop taking EXALGO while breastfeeding, your baby may have withdrawal symptoms. See the list of withdrawal symptoms above.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicines may cause serious or life-threatening medical problems when taken with EXALGO. Sometimes, the doses of certain medicines and EXALGO need to be changed if used together. Be especially careful about other medicines that make you sleepy such as:

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| • other pain medicines | • anti-anxiety medicines |
| • antidepressant medicines | • muscle relaxants |
| • sleeping pills | • anti-nausea medicines |
| • antihistamines | • tranquilizers |

Do not take EXALGO if you already take a monoamine oxidase inhibitor medicine (MAOI) or within 14 days after you stop taking an MAOI medicine.

Do not take any new medicine while using EXALGO until you have talked to your healthcare provider or pharmacist. They will tell you if it is safe to take other medicines while you are taking EXALGO. Ask your healthcare provider if you are not sure if your medicine is one listed above.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take EXALGO?

- **Take EXALGO exactly as prescribed by your healthcare provider. Do not change your dose unless your healthcare provider tells you to.**
- **Take EXALGO one time each day at the same time every day.**

- **Swallow the EXALGO tablet whole. Do not break, chew, crush, or dissolve EXALGO before swallowing, or inject the contents of EXALGO. See "What is the most important information I should know about EXALGO?"** Tell your healthcare provider if you cannot swallow EXALGO whole. You need to take a different pain medicine.
- **EXALGO can be taken with or without food.**
- The EXALGO tablet is contained in a hard shell that does not dissolve in your body. The tablet shell passes through your body in your stool. You may notice something that looks like a tablet in your bowel movement. This is normal.
- Call your healthcare provider if the dose of EXALGO that you are taking does not control your pain.
- **If you stop taking EXALGO for 3 or more days**, call your healthcare provider before restarting the medicine.
- If you are not sure if you have taken your dose, do not take another dose. **Taking more EXALGO than prescribed may cause you to overdose.** If you are not sure what to do, call your healthcare provider.
- If you take too much EXALGO or overdose, call 911 or get emergency help right away.
- **Do not stop taking EXALGO without talking to your healthcare provider.** Opioid medicines such as EXALGO can cause physical dependence. You should not suddenly stop taking EXALGO because you may become sick with uncomfortable withdrawal symptoms. If your healthcare provider decides you no longer need EXALGO, ask how to slowly stop taking this medicine to avoid uncomfortable withdrawal symptoms.

What should I avoid while taking EXALGO?

- **Do not drive or operate heavy machinery, or do other dangerous activities,** until you know how EXALGO affects how alert you are. EXALGO can make you sleepy, and cause you to feel dizzy or lightheaded. This may affect your ability to think and react. Ask your healthcare provider when it is okay to do these activities.
- **Do not drink alcohol or use prescription or non-prescription medicines that contain alcohol while taking EXALGO.** Using alcohol while taking EXALGO may cause you to overdose and die.

What are the possible side effects of EXALGO?

EXALGO can cause serious side effects that can lead to death.

- **See "What is the most important information I should know about EXALGO?"**

Call your healthcare provider or get emergency medical help if you:

- **have trouble breathing**
- **have extreme drowsiness with slowed breathing**
- **have shallow breathing (little chest movement with breathing)**
- **feel faint, dizzy, confused, or have other unusual symptoms**

These can be symptoms that you have taken too much (overdose) EXALGO or the dose is too high for you. **These symptoms may lead to serious problems or death if not treated right away.**

- **Drop in your blood pressure.** This can make you feel dizzy if you get up too fast from sitting or lying down. Low blood pressure is also more likely to happen if you take other medicines that can also lower your blood pressure. Severe low blood pressure can happen if you lose blood or take certain other medicines.
- **Symptoms of stomach or intestinal blockage.** EXALGO tablets do not change shape when they pass through your stomach and intestine. People who have certain stomach or intestinal problems, such as narrowing (stricture), or who have had surgery in these areas may get symptoms of a blockage. Tell your healthcare provider right away if you get any of these symptoms:
 - vomiting
 - severe constipation
 - abdominal pain
 - abdominal distension
- **Allergic reactions.** EXALGO contains sodium metabisulfite, a sulfite that may cause allergic-type reactions. Symptoms of an allergic reaction to EXALGO and sulfites may include:
 - feel dizzy or faint
 - trouble breathing
 - pounding heart beat
 - chest pain
 - swelling of the face, throat, or tongue
 - feeling of doom
- **Physical dependence.** Stopping EXALGO suddenly can make you sick with withdrawal symptoms because your body has become used to it. Talk to your healthcare provider about slowly stopping EXALGO. Physical dependence is not the same thing as addiction. Tell your healthcare provider if you have any of the following symptoms of withdrawal while slowly stopping EXALGO:
 - feel restless
 - tearing eyes
 - runny nose
 - yawning
 - sweating
 - chills or hair on your arms “standing up”
 - muscle aches, backache, joint pain
 - weakness
 - dilated pupils of your eyes
 - feel irritable or anxious
 - nausea, loss of appetite, vomiting, diarrhea
 - increase in your blood pressure, breathing faster, or your heart beats faster
 - sleep problems
- **There is a chance of abuse or addiction with EXALGO.** The chance is higher if you are, or have been addicted to or abused other medicines, street drugs, or alcohol, or if you have a history of mental problems.

The most common side effects of EXALGO include:

- constipation
- nausea
- drowsiness or sleepiness
- headache
- vomiting
- tiredness
- dizziness

Constipation (not enough or hard bowel movements) is a common side effect of pain medicines (opioids) including EXALGO and is unlikely to go away without treatment. Talk to your healthcare provider about dietary changes, the use of laxatives (medicines to treat constipation) and stool softeners to prevent or treat constipation while taking EXALGO.

These are not all the possible side effects of EXALGO. Talk to your healthcare provider if you have any side effects that bother you or do not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store EXALGO?

- Store EXALGO at 59°F to 86°F (15°F to 30°).
- Keep EXALGO in the container it comes in.
- Keep EXALGO dry and away from heat.
- **After you stop taking EXALGO flush any unused tablets down the toilet.**

Keep EXALGO in a safe and secure place away from children.

General information about EXALGO

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use EXALGO for a purpose for which it was not prescribed. Do not give EXALGO to other people, even if they have the same symptoms you have. EXALGO can harm other people and even cause death.

Sharing EXALGO is against the law.

This Medication Guide summarizes the most important information about EXALGO. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about EXALGO that is written for healthcare professionals.

For more information go to www.exalgo.com or call the Product Monitoring Department, Neuromed Pharmaceuticals at 1-866-377-3485

What are the ingredients of EXALGO?

- **Active Ingredient:** hydromorphone hydrochloride.
- **Inactive Ingredients:** butylated hydroxytoluene, cellulose acetate, iron oxide black, hypromellose, lactose anhydrous, lactose monohydrate, magnesium stearate; polyethylene glycol, polyethylene oxide, povidone; sodium chloride, titanium dioxide and triacetin. The 8 mg tablets also contain ferric oxide red. The 12 and 16mg tablets also contain ferric oxide yellow.

Manufactured by : ALZA Corporation, 700 Eubanks Drive, Vacaville, CA 95688 for Neuromed Pharmaceuticals, Inc., Conshohocken, PA 19428

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