

Medication Guide

Hydromorphone Hydrochloride (HYE-droe-MOR-fone HYE-droe-KLOR-ide) Extended-Release Tablets, CII

Hydromorphone Hydrochloride Extended-Release Tablets are:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage severe and persistent pain that requires an extended treatment period with a daily opioid pain medicine when other pain 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 to be taken on an “as needed” basis.

Important information about hydromorphone hydrochloride extended-release tablets:

- **Get emergency help or call 911 right away if you take too much hydromorphone hydrochloride extended-release tablets (overdose).** When you first start taking hydromorphone hydrochloride extended-release tablets, 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. Talk to your healthcare provider about naloxone, a medicine for the emergency treatment of an opioid overdose.
- Taking hydromorphone hydrochloride extended-release tablets with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.
- Never give anyone else your hydromorphone hydrochloride extended-release tablets. They could die from taking it. Selling or giving away hydromorphone hydrochloride extended-release tablets is against the law.
- Store hydromorphone hydrochloride extended-release tablets securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

Do not take hydromorphone hydrochloride extended-release tablets if you have:

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

Before taking hydromorphone hydrochloride extended-release tablets, tell your healthcare provider if you have a history of:

- head injury, seizures
- problems urinating
- abuse of street or prescription drugs, alcohol addiction, opioid overdose, or mental health problems.
- liver, kidney, thyroid problems
- pancreas or gallbladder problems
- allergy to sulfites

Tell your healthcare provider if you are:

- noticing your pain getting worse. If your pain gets worse after you take hydromorphone hydrochloride extended-release tablets, do not take more of hydromorphone hydrochloride extended-release tablets without first talking to your healthcare provider. Talk to your healthcare provider if the pain that you have increases, if you feel more sensitive to pain, or if you have new pain after taking hydromorphone hydrochloride extended-release tablets.
- **Are pregnant or planning to become pregnant.** Use of hydromorphone hydrochloride extended-release tablets for an extended period of time 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 hydromorphone hydrochloride extended-release tablets. It may harm your baby.
- living in a household where there are small children or someone who has abused street or prescription drugs
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking hydromorphone hydrochloride extended-release tablets with certain other medicines can cause serious side effects.

When taking hydromorphone hydrochloride extended-release tablets:

- Do not change your dose. Take hydromorphone hydrochloride extended-release tablets exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- 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 hydromorphone hydrochloride extended-release tablets whole. Do not cut, break, chew, crush, dissolve, snort, or inject hydromorphone hydrochloride extended-release tablets 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 hydromorphone hydrochloride extended-release tablets without talking to your healthcare provider.**
- Hydromorphone hydrochloride extended-release tablets are contained in a hard tablet shell that you may see in your bowel movement; this is normal.
- Dispose of expired, unwanted, or unused hydromorphone hydrochloride extended-release tablets by promptly flushing down the toilet, if a drug take-back option is not readily available. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

While taking hydromorphone hydrochloride extended-release tablets, DO NOT:

- Drive or operate heavy machinery, until you know how hydromorphone hydrochloride extended-release tablets affects you. Hydromorphone hydrochloride extended-release tablets 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 hydromorphone hydrochloride extended-release tablets may cause you to overdose and die.

The possible side effects of hydromorphone hydrochloride extended-release tablets 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 or call 911 right away 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 hydromorphone hydrochloride extended-release tablets. Call your healthcare provider 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**

Medication Guide available at <http://camberpharma.com/medication-guides>

Manufactured by:

Ascent Pharmaceuticals, Inc.

Central Islip, NY 11722

Manufactured for:

Camber Pharmaceuticals, Inc.

Piscataway, NJ 08854

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

Revision: 10/23