

Medication Guide

Hydromorphone Hydrochloride 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 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 hydromorphone hydrochloride extended-release tablets:

- **Get emergency help right away if you take too many 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.
- Never give anyone else your hydromorphone hydrochloride extended-release tablets. They could die from taking it. Store hydromorphone hydrochloride extended-release tablets away from children and in a safe place to prevent stealing or abuse. Selling or giving away hydromorphone hydrochloride extended-release tablets is against the law.

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
- 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 hydromorphone hydrochloride extended-release tablets during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **breastfeeding.** Hydromorphone hydrochloride passes into breast milk and may harm your baby.
- 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.
- 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.
- After you stop taking hydromorphone hydrochloride extended-release tablets, flush any unused tablets down the toilet.

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

- Drive or operate heavy machinery, until you know how hydromorphone hydrochloride extended-release tablets affect 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 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 hydromorphone hydrochloride extended-release tablets. 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**

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

Mallinckrodt™