Medication Guide

Hydromorphone hydrochloride (HYE-droe-MOR-fone HYE-droe-KLOR-ide) Tablets, CII

Hydromorphone hydrochloride tablets are:

- Strong prescription pain medicines that contains an opioid (narcotic) that is used to manage pain severe enough to require an opioid analgesic, when other pain treatments such as non-opioid pain medicines do not treat your pain well enough or you cannot tolerate them.
- Opioid pain medicines 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.

Important information about hydromorphone hydrochloride tablets:

- **Get emergency help or call 911 right away if you take too much hydromorphone hydrochloride tablets (overdose).** When you first start taking **hydromorphone hydrochloride 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 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 tablets. They could die from taking it. Selling or giving away hydromorphone hydrochloride tablets is against the law.
- Store hydromorphone hydrochloride 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 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 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

Tell your healthcare provider if you are:

- **Noticing your pain getting worse.** If your pain gets worse after you take hydromorphone hydrochloride tablets, do not take more of hydromorphone hydrochloride 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 tablets.
- **Pregnant or planning to become pregnant.** Use of hydromorphone hydrochloride 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.** Hydromorphone hydrochloride pass into breast milk and may harm your baby. Carefully observe infants for increased sleepiness (more than usual), breathing difficulties, or limpness. Seek immediate medical care if you notice these signs.
- Living in a household where there are small children or someone who has abused street or a prescription drugs.
- Taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking hydromorphone hydrochloride tablets with certain other medicines can cause serious side effects that could lead to death.

When taking hydromorphone hydrochloride tablets:

- Do not change your dose. Take hydromorphone hydrochloride tablets exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- For acute (short-term) pain, you may only need to take hydromorphone hydrochloride tablets for a few days. You may have some hydromorphone hydrochloride tablets left over that you did not use. See disposal information at the bottom of this section for directions on how to safely throw away (dispose of) your unused hydromorphone hydrochloride tablets.
- Do not take more than your prescribed dose. If you miss a dose, take your next dose at your usual time.
- Call your healthcare provider if the dose you are taking does not control your pain.
- If you have been taking hydromorphone hydrochloride tablets regularly, do not stop taking hydromorphone hydrochloride tablets without talking to your healthcare provider.
- Dispose of expired, unwanted, or unused hydromorphone hydrochloride 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 tablets DO NOT:

- Drive or operate heavy machinery, until you know how hydromorphone hydrochloride tablets affects you. Hydromorphone hydrochloride tablets can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol. Using products containing alcohol during treatment with hydromorphone hydrochloride tablets may cause you to overdose and die.

The possible side effects of hydromorphone hydrochloride tablets:

- 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 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 or call Ascent Pharmaceuticals, Inc., at 1-855-221-1622.**

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This Medication Guide has been approved by the U.S. Food and Drug Administration. Rev: 12/24