

Medication Guide

Oxymorphone hydrochloride (OX-i-MOR-fone HYE-droe-KLOR-ide) tablets, for oral use, CII

Oxymorphone hydrochloride tablets are:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage short-term (acute) pain when other pain treatments such as non-opioid pain medicines do not treat your pain well enough or you cannot tolerate them.
- An 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.

Important information about oxymorphone hydrochloride tablets:

- **Get emergency help right away if you take too much oxymorphone hydrochloride tablets (overdose).** When you first start taking oxymorphone 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.
- Taking oxymorphone 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 oxymorphone hydrochloride tablets. They could die from taking it. Selling or giving away oxymorphone hydrochloride tablets is against the law.
- Store oxymorphone 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 oxymorphone 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 oxymorphone hydrochloride tablets, tell your healthcare provider if you have a history of:

- head injury, seizures
- liver, kidney, thyroid problems
- 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 oxymorphone hydrochloride tablets during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **breastfeeding.** Oxymorphone hydrochloride tablets passes into breast milk and may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking oxymorphone hydrochloride tablets with certain other medicines can cause serious side effects that could lead to death.

When taking oxymorphone hydrochloride tablets:

- Do not change your dose. Take oxymorphone hydrochloride tablets exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- Oxymorphone hydrochloride tablets should be taken on an empty stomach, at least one hour prior to or two hours after eating.
- Take your prescribed dose at the same time every day. 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 oxymorphone hydrochloride tablets regularly, do not stop taking oxymorphone hydrochloride tablets without talking to your healthcare provider.
- Dispose of expired, unwanted, or unused oxymorphone 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 oxymorphone hydrochloride tablets DO NOT:

- Drive or operate heavy machinery, until you know how oxymorphone hydrochloride tablets affects you. Oxymorphone 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 oxymorphone hydrochloride tablets may cause you to overdose and die.

The possible side effects of oxymorphone 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 if you have:

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue or throat or hands, hives, itching, rash, 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 oxymorphone hydrochloride tablets. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or call XLCare Pharmaceuticals, Inc. at 1-866-495-1995. **For more information go to dailymed.nlm.nih.gov**

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