

Medication Guide

Oxycodone Hydrochloride (ox" i koe' done hye" droe klor' ide) and Ibuprofen (eye" bue proe' fen) Tablets CII

Oxycodone hydrochloride and ibuprofen tablets are:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage acute moderate to severe 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 oxycodone hydrochloride and ibuprofen tablets:

- **Get emergency help right away if you take too many oxycodone hydrochloride and ibuprofen tablets (overdose).** When you first start taking oxycodone hydrochloride and ibuprofen tablets, when your dose is changed, or if you take too many (overdose), serious or life-threatening breathing problems that can lead to death may occur.
- Taking oxycodone hydrochloride and ibuprofen 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 oxycodone hydrochloride and ibuprofen tablets. They could die from taking them. Store oxycodone hydrochloride and ibuprofen tablets away from children and in a safe place to prevent stealing or abuse. Selling or giving away oxycodone hydrochloride and ibuprofen tablets is against the law.

Do not take oxycodone hydrochloride and ibuprofen tablets:

- if you have severe asthma, trouble breathing, or other lung problems
- if you have a bowel blockage or have narrowing of the stomach or intestines
- right before or after heart bypass surgery
- if you have had an asthma attack, hives, or other allergic reaction with aspirin or any other nonsteroidal anti-inflammatory drugs (NSAIDs)

Before taking oxycodone hydrochloride and ibuprofen 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	• asthma • high blood pressure

Tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** Prolonged use of oxycodone hydrochloride and ibuprofen tablets during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated. Starting at 30 weeks gestation, use of oxycodone hydrochloride and ibuprofen tablets, should be avoided as premature closure of the ductus arteriosus may occur.
- **breastfeeding.** Oxycodone hydrochloride and ibuprofen passes into breast milk and may harm your baby.

- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking oxycodone hydrochloride and ibuprofen tablets with certain other medicines can cause serious side effects that could lead to death.

When taking oxycodone hydrochloride and ibuprofen tablets:

- Do not change your dose. Take oxycodone hydrochloride and ibuprofen exactly as prescribed by your healthcare provider.
- 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 oxycodone hydrochloride and ibuprofen tablets regularly, do not stop taking oxycodone hydrochloride and ibuprofen tablets without talking to your healthcare provider.
- After you stop taking oxycodone hydrochloride and ibuprofen tablets, flush any unused tablets down the toilet.

While taking oxycodone hydrochloride and ibuprofen tablets DO NOT:

- Drive or operate heavy machinery, until you know how oxycodone hydrochloride and ibuprofen tablets affect you. Oxycodone hydrochloride and ibuprofen 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 oxycodone hydrochloride and ibuprofen tablets may cause you to overdose and die.

The possible side effects of oxycodone hydrochloride and ibuprofen tablets:

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain, gas, heartburn, diarrhea, new or worse high blood pressure, heart failure, liver problems including liver failure, low red blood cells (anemia), life-threatening skin reactions, life-threatening allergic reactions. 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, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, slurred speech, weakness in one side of your body or mental changes such as confusion. These are not all the possible side effects of oxycodone hydrochloride and ibuprofen 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.**

For more information about oxycodone hydrochloride and ibuprofen tablets, call Actavis at 1-800-432-8534.

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

Issued: September 2016

Manufactured by:
Actavis Elizabeth LLC
Elizabeth, NJ 07207 USA

Distributed by:
Actavis Pharma, Inc.
Parsippany, NJ 07054 USA

40-9065

(MG 41-1223/0916)