

## 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) and a non-steroidal anti-inflammatory drug (NSAID), that is used to manage short-term pain (less than 7 days), 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.
- NSAIDs are used to treat pain and redness, swelling, and heat (inflammation) from medical conditions such as different types of arthritis, menstrual cramps, and other types of short-term pain.

#### **Important information about Oxycodone Hydrochloride and Ibuprofen Tablets:**

- **Get emergency help right away if you take too much 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 much (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 it. 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.

#### **Oxycodone Hydrochloride and Ibuprofen Tablets contain an NSAID. NSAIDs can cause serious side effects including:**

- **Increased risk of a heart attack or stroke that can lead to death.** This risk may happen early in treatment and may increase:
  - with increasing doses of medicine containing NSAIDs
  - with longer use of medicine containing NSAIDs

#### **Do not take NSAIDs right before or after a heart surgery called a “coronary artery bypass graft (CABG).”**

**Avoid taking NSAIDs, after a recent heart attack, unless your healthcare provider tells you to. You may have an increased risk of another heart attack if you take NSAIDs after a recent heart attack.**

- **Increased risk of bleeding, ulcers, and tears (perforation) of the esophagus (tube leading from the mouth to the stomach), stomach and intestines:**
  - any time during use
  - without warning symptoms
  - that may cause death

#### **The risk of getting an ulcer or bleeding increases with:**

- past history of stomach ulcers, or stomach or intestinal bleeding with use of NSAIDs

- taking medicines called “corticosteroids”, “anticoagulants”, “SSRIs”, or “SNRIs”
- increasing doses of NSAIDs
- longer use of NSAIDs
- smoking
- drinking alcohol
- older age
- poor health
- advanced liver disease
- bleeding problems

**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
- if you have had an asthma attack, hives, or other allergic reaction with aspirin or any other NSAIDs, or opioid medicine.
- right before or after heart bypass surgery

**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
- have high blood pressure
- have asthma
- 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 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. Talk to your healthcare provider if you are considering taking Oxycodone Hydrochloride and Ibuprofen Tablets during pregnancy. **You should not take NSAIDs after 29 weeks of pregnancy.**
- **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 Tablets exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- Take your prescribed dose at the every 6 hours as needed for pain. 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, new or worse high blood pressure, heart failure, liver problems including liver failure, kidney problems including kidney 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:**

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| • trouble breathing or shortness of breath | • agitation                                 |
| • fast heartbeat                           | • high body temperature                     |
| • chest pain                               | • trouble walking                           |
| • swelling of your face, tongue, or throat | • stiff muscles                             |
| • extreme drowsiness                       | • mental changes such as confusion          |
| • lightheadedness when changing positions  | • weakness in one part or side of your body |
| • fainting or feel faint                   | • slurred speech                            |
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**Stop Oxycodone Hydrochloride and Ibuprofen Tablets and call your healthcare provider right away if you have any of the following symptoms:**

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| • nausea                          | • flu-like symptoms  |
| • more tired or weaker than usual | • vomit blood  |
| • diarrhea                        | • there is blood in your bowel movement or it is black and sticky like tar |
| • itching                         | • unusual weight gain  |
| • your skin or eyes look yellow   | • skin rash or blisters with fever   |
| • indigestion or stomach pain     | • swelling of the arms and legs, hands and feet                            |
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**Other information:**

- Aspirin is an NSAID medicine but it does not increase the chance of a heart attack. Aspirin can cause bleeding in the brain, stomach, and intestines. Aspirin can also cause ulcers in the stomach and intestines.
- Some NSAID medicines are sold in lower doses without a prescription (over-the-counter). Talk to your healthcare provider before using over-the-counter NSAIDs for more than 10 days.

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](https://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.**

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