

Medication Guide

Oxycodone and Aspirin (ox'' i koe' done and as' pir in)

Tablets, USP, CII

Oxycodone and aspirin tablets are:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage moderate to moderately severe, 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 and aspirin tablets:

- **Get emergency help right away if you take too many oxycodone and aspirin tablets (overdose).** When you first start taking oxycodone and aspirin 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 oxycodone and aspirin tablets. They could die from taking them. Store oxycodone and aspirin tablets away from children and in a safe place to prevent stealing or abuse. Selling or giving away oxycodone and aspirin tablets are against the law.

Do not take oxycodone and aspirin tablets if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.
- known hypersensitivity to oxycodone, aspirin, or any other component of this product and in any situation where opioids or aspirin are contraindicated. Aspirin is contraindicated for patients with hemophilia.
- **Reye Syndrome: Aspirin should not be used in children or teenagers for viral infections, with or without fever, because of the risk of Reye syndrome with concomitant use of aspirin in certain viral illnesses**
- known allergy to nonsteroidal anti-inflammatory drug products and in patients with the syndrome of asthma, rhinitis, and nasal polyps. Aspirin may cause severe urticaria, angioedema, or bronchospasm (asthma).
- known hypersensitivity to oxycodone. Oxycodone is contraindicated in any situation where opioids are contraindicated including patients with significant respiratory depression (in unmonitored settings or the absence of resuscitative equipment) and patients with acute or severe bronchial asthma or hypercarbia. Oxycodone is contraindicated in the setting of suspected or known paralytic ileus.

Before taking oxycodone and aspirin 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 oxycodone and aspirin tablets during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **breastfeeding.** Oxycodone and aspirin passes into breast milk and may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking oxycodone and aspirin tablets with certain other medicines can cause serious side effects that could lead to death.

When taking oxycodone and aspirin tablets:

- Do not change your dose. Take oxycodone and aspirin tablets exactly as prescribed by your healthcare provider.
- Take your prescribed dose every 6 hours 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 and aspirin tablets regularly, do not stop taking oxycodone and aspirin tablets without talking to your healthcare provider.
- After you stop taking oxycodone and aspirin tablets, flush any unused tablets down the toilet.

While taking oxycodone and aspirin tablets DO NOT:

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

The possible side effects of oxycodone and aspirin 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, 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 oxycodone and aspirin 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 call Actavis at 1-800-272-5525.

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

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