

What is PROLATE® ORAL SOLUTION?

PROLATE is a prescription drug for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. PROLATE combines two powerful pain relievers, oxycodone and acetaminophen, in a unique formulation that balances efficacy while reducing your risk for side effects. Your doctor may prescribe PROLATE to treat pain after surgery or any pain severe enough to require an opioid analgesic where alternative treatments are inadequate.

What is the most important information you should know about PROLATE?

PROLATE® (oxycodone and acetaminophen tablets, CII) is a strong prescription pain medicine that contains an opioid (narcotic) that is used to manage pain severe enough to require an opioid medication, and for which alternative treatments such as non-opioid pain medicines do not treat your pain well enough or you cannot tolerate them.

Opioid pain medicines 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.

Get emergency help right away if you take too much PROLATE (overdose). When you first start taking PROLATE, 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 PROLATE 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 PROLATE. They could die from taking it. Store PROLATE away from children and in a safe place to prevent stealing or abuse. Selling or giving away PROLATE is against the law.

Who should not take PROLATE?

Do not take PROLATE if you:

- Have severe asthma, trouble breathing, or other lung problems

- Have a bowel blockage or have narrowing of the stomach or intestines
- Have a known allergy or hypersensitivity to oxycodone, acetaminophen, or any ingredient in PROLATE

Before you take PROLATE, tell your healthcare provider if you:

- Have a history of head injury or any seizure disorder
- Have or have had liver, kidney or thyroid problems
- Have problems urinating
- Have or have had pancreas or gallbladder problems
- Have ever abused street or prescription drugs, been addicted to alcohol, or have any history of mental health problem

Also tell your healthcare provider if you are:

- **Pregnant or planning to become pregnant.** Using PROLATE for long periods during pregnancy can cause withdrawal symptoms in your newborn baby that can be dangerous or life-threatening if not recognized or treated.
- **Breastfeeding.** PROLATE passes into breast milk and may harm your baby.

It is important that you tell your healthcare provider about all medicines that you take, including over-the-counter medications and nutritional supplements. Taking PROLATE with certain other medicines can cause serious side effects that could lead to death.

Tell you healthcare provider about all medicines you take, including any of the following:

- **Medicines that affect an enzyme in your body called CYP3A4**, such as certain antibiotics like erythromycin, anti-fungal medicines like ketoconazole, and antiviral medicines like ritonavir.
- **Benzodiazepines**, or other drugs that affect your central nervous system such as sedatives, tranquilizers, muscle relaxants or anti-anxiety medicines
- **Any other medication containing acetaminophen.** Acetaminophen (one of the medicines in PROLATE) can cause liver failure, especially at higher doses. Many

cases of liver injury from acetaminophen are the result of patients using more than one acetaminophen-containing product.

Ask your healthcare professional if you are unsure whether any of the medicines you take are in any of the categories listed above.

Important information about taking PROLATE:

- Do not change your dose. Take PROLATE exactly as prescribed by your healthcare provider.
- Take your prescribed dose 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. Do not attempt to take more tablets than prescribed to get additional pain relief.
- If you have been taking PROLATE regularly, do not stop taking PROLATE without talking to your healthcare provider.
- After you stop taking PROLATE, dispose of unused tablets by flushing them down the toilet.

While taking PROLATE, make sure you DO NOT:

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

What are the possible side effects of PROLATE?

The most common side effects of PROLATE are constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness and abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.

Life-threatening breathing difficulties are possible with opioid medicines like PROLATE, even when used as recommended. The risks for severe breathing

problems may be higher in the elderly or in people with other breathing disorders or lung conditions.

Get emergency medical help if you have any of the following while taking PROLATE:

- 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.

USE ONLY AS DIRECTED BY YOUR HEALTHCARE PROFESSIONAL

These are not all the possible side effects of PROLATE. Talk to your healthcare provider or pharmacist for more information or for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or by visiting www.fda.gov/medwatch.

For more dosing information, please [click here](#) for full Prescribing Information and Medication Guide.