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MEDICATION GUIDE
PROLATE®
(Oxycodone and Acetaminophen Tablets), CII

PROLATE® is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage pain, severe enough to require an opioid analgesic and for which alternative treatments are inadequate and 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 PROLATE®:

- **Get emergency help or call 911 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. Talk to your healthcare provider about naloxone, a medicine for the emergency treatment of an opioid overdose.
- 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. Selling or giving away PROLATE® is against the law.
- Store PROLATE® securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

Do not take PROLATE® 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, acetaminophen, or any ingredient in PROLATE®

Before taking PROLATE®, 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, opioid overdose, or mental health problems

Tell your healthcare provider if you are:

- **Pregnant or planning to become pregnant.** Prolonged use of PROLATE® during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **Breastfeeding.** PROLATE® passes into breast milk and may harm your baby.

- Living in a household where there are small children or someone who has abused street or prescription drugs.
- Taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking PROLATE® with certain other medicines can cause serious side effects that could lead to death.

When taking PROLATE®:

- Do not change your dose. Take PROLATE® exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- 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.
- If you have been taking PROLATE® regularly, do not stop taking PROLATE® without talking to your healthcare provider.
- Dispose of expired, unwanted, or unused PROLATE® 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 PROLATE® DO NOT:

- Drive or operate heavy machinery, until you know how PROLATE® affects you. PROLATE® 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 PROLATE® may cause you to overdose and die.

The possible side effects of PROLATE®:

- 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 or call 911 right away 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 PROLATE®. 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**

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

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