

MEDICATION GUIDE PROLATE Oxycodone Hydrochloride and Acetaminophen Oral Solution, CII
<p>Prolate is:</p> <ul style="list-style-type: none"> 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.
<p>Important information about Prolate:</p> <ul style="list-style-type: none"> 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. 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. Talk to your healthcare provider about naloxone, a medicine for the emergency treatment of an opioid overdose. 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.
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<p>Before taking Prolate, tell your healthcare provider if you have a history of:</p> <ul style="list-style-type: none"> 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 <p>Tell your healthcare provider if you are:</p> <ul style="list-style-type: none"> 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.
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Prolate
(Oxycodone Hydrochloride and Acetaminophen Oral Solution, 10 mg/300 mg per 5 mL), CII
 Rx only

Code 1172A99

Rev. 05/21

Product Information

Flat Size: 12" x 24"
Folded Size: 1.25" x 2"
Number of Panels: 120 Panel

Paper Weight: 26# Opaque Offset
Ink: Food Grade Black

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.**

Distributed by: Forte Bio-Pharma LLC, Las Vegas, NV 89113

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James B. Harris
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 President
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