Medication Guide ROXYBOND (\'räk-sē- 'bänd\) (oxycodone hydrochloride) tablets USP, CII

ROXYBOND is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage pain severe enough to require an opioid pain medicine, when other pain treatments such as nonopioid 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 ROXYBOND:

- Get emergency help right away if you take too much ROXYBOND (overdose). When you first start taking ROXYBOND, when your dose is changed, or if you take too much (overdose), serious or lifethreatening breathing problems that can lead to death may occur.
- Taking ROXYBOND 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 ROXYBOND. They could die from taking it. Store ROXYBOND away from children and in a safe place to prevent stealing or abuse. Selling or giving away ROXYBOND is against the law.

Do not take ROXYBOND if you have:

- · severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.
- allergy to oxycodone.

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

When taking ROXYBOND:

- Do not change your dose. Take ROXYBOND exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- Take your prescribed dose every 4 to 6 hours. 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 ROXYBOND regularly, do not stop taking ROXYBOND without talking to your healthcare provider.
- After you stop taking ROXYBOND, flush any unused tablets down the toilet.

While taking ROXYBOND DO NOT:

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

The possible side effects of ROXYBOND are:

- 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 ROXYBOND. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088. For more information go to dailymed.nlm.nih.gov

Manufactured for Daiichi Sankyo, Inc.

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

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