

MEDICATION GUIDE
Oxycodone Hydrochloride (ox-ee-CO-dohn) (CII)
Oral Solution

IMPORTANT: Keep Oxycodone Hydrochloride Oral Solution in a safe place away from children. Accidental use by a child is a medical emergency and can cause death. If a child accidentally takes Oxycodone Hydrochloride Oral Solution, get emergency help right away.

Read the Medication Guide that comes with Oxycodone Hydrochloride Oral Solution before you start taking it and each time you get a new prescription. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about Oxycodone Hydrochloride Oral Solution?

Oxycodone Hydrochloride Oral solution can cause serious side effects, including, death.

- 1. Take Oxycodone Hydrochloride Oral Solution exactly as prescribed by your healthcare provider.** If you take the wrong dose or strength of Oxycodone Hydrochloride Oral Solution, you could overdose and die.
2. It is especially important when you take Oxycodone Hydrochloride Oral Solution that you know exactly what dose and strength to take, and the right way to measure your medicine. Your healthcare provider or pharmacist should show you the right way to measure your medicine.
- 3. Oral Syringe.** Always use the oral syringe provided with Oxycodone Hydrochloride Oral Solution, 100 mg per 5 mL (20 mg per mL) to help make sure you measure the right amount.
- 4. Do not drink alcohol.** Using alcohol with Oxycodone Hydrochloride Oral Solution may increase your risk of dangerous side effects, including death.
- 5. Opioid Tolerance. Do not take oxycodone Hydrochloride Oral Solution, 100 mg per 5 mL (20 mg per mL), unless you are “opioid tolerant.”** Opioid tolerant means that you take another opioid medicine for your constant (around the clock) pain and your body is used to it.

What is Oxycodone Hydrochloride Oral Solution?

Oxycodone Hydrochloride Oral Solution is in a group of drugs called narcotic pain relievers. Oxycodone Hydrochloride Oral Solution is only for adults who have moderate to severe pain.

- A prescription medicine that is used to manage moderate to severe pain that is expected to last a short period of time (acute), and pain that continues around-the-clock and is expected to last for a long period of time (chronic).

- Oxycodone Hydrochloride Oral Solution is a federally controlled substance (CII) because it is a strong opioid pain medicine that can be abused by people who abuse prescription medicines or street drugs.
- Prevent theft, misuse or abuse. Keep Oxycodone Hydrochloride Oral Solution in a safe place to keep it from being stolen. Oxycodone Hydrochloride Oral Solution can be a target for people who misuse or abuse prescription medicines or street drugs.
- Never give Oxycodone Hydrochloride Oral Solution to anyone else, even if they have the same symptoms you have. It may harm them or even cause death.
- Selling or giving away this medicine is against the law.
- It is not known if Oxycodone Hydrochloride Oral Solution is safe and effective in children under age 18 years of age.
- Oxycodone Hydrochloride 100 mg per 5 mL (20 mg per mL) Oral Solution is only for adults with moderate to severe pain who are already using an opioid narcotic pain medicine and have been using this medicine continuously for several weeks or longer.

Who should not take Oxycodone Hydrochloride Oral Solution?

Do not take Oxycodone Hydrochloride Oral Solution if you:

- **are allergic to oxycodone, oxycodone salts, or any of the ingredients in Oxycodone Hydrochloride Oral Solution.** See the end of this Medication Guide for a complete list of ingredients in Oxycodone Hydrochloride Oral Solution.
- are having breathing problems and there is no emergency medical equipment nearby
- are having an asthma attack or have severe asthma, trouble breathing, or lung problems
- have a bowel blockage called paralytic ileus

What should I tell my healthcare provider before taking Oxycodone Hydrochloride Oral Solution?

Before taking Oxycodone Hydrochloride Oral Solution, tell your healthcare provider if you:

- have trouble breathing or lung problems
- have had a head injury
- have liver or kidney problems
- have adrenal gland problems, such as Addison's disease
- have severe scoliosis that affects your breathing
- have thyroid problems
- have problems urinating or enlargement of your prostate
- have or had convulsions or seizures
- have a past or present drinking problems or alcoholism

- have hallucinations (seeing or hearing things that are not really there) or other severe mental problems
- have constipation or other bowel problems
- have problems with your pancreas or gallbladder
- have past or present substance abuse or drug addiction
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not know if Oxycodone Hydrochloride Oral Solution will harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant.

If you take Oxycodone Hydrochloride Oral Solution regularly before your baby is born, your newborn baby may have signs of withdrawal because their body has become used to the medicine. Signs of withdrawal in a newborn baby can include:

- | | |
|---------------------|---------------------------------------|
| ○ irritability | ○ vomiting |
| ○ being very active | ○ diarrhea or more stools than normal |
| ○ problems sleeping | ○ weight loss |
| ○ high pitched cry | |
| ○ shaking (tremors) | |

If you are taking Oxycodone Hydrochloride Oral Solution right before your baby is born, your baby could have breathing problems.

- are breast-feeding or plan to breastfeed. Some Oxycodone Hydrochloride Oral Solution passes into your breast milk. A nursing baby could become very sleepy or have difficulty breathing or feeding well. If you stop breastfeeding, your baby may have withdrawal symptoms. See the list of withdrawal symptoms above. You and your healthcare provider should decide if you will take Oxycodone Hydrochloride Oral Solution or breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Sometimes the doses of medicines that you take with Oxycodone Hydrochloride Oral Solution may need to be changed if used together. Be especially careful about taking other medicines that make you sleepy such as:

- | | |
|-----------------------|---------------------------|
| sleeping pills | anti-anxiety medicines |
| other pain medicines | anti-depressants |
| anti-nausea medicines | monoamine oxidase |
| tranquilizers | inhibitors (MAOIs) |
| muscle relaxants | anticholinergic medicines |
| antihistamines | |

Ask your healthcare provider if you are not sure if your medicine is one listed above.

- Do not take other medicines while using Oxycodone Hydrochloride Oral Solution until you have talked with your healthcare provider or pharmacist. They will tell you if it is safe to take other medicines with Oxycodone Hydrochloride Oral Solution.

Know the medicines you take. Keep a list of them and show it to show your healthcare provider and pharmacist when you get a new medicine.

How should I take Oxycodone Hydrochloride Oral Solution?

- See **“What is the most important information I should know about Oxycodone Hydrochloride Oral Solution?”**
- **Take Oxycodone Hydrochloride Oral Solution exactly as prescribed.** Do not change your dose unless your healthcare provider tells you to. Your healthcare provider may change your dose after seeing how the medicine affects you. Call your healthcare provider if your pain is not well controlled with your prescribed dose of Oxycodone Hydrochloride Oral Solution.
- **Make sure you understand exactly how to measure your dose.** Always use the oral dropper provided with your Oxycodone Hydrochloride Oral Solution, 100 mg per 5 mL (20 mg per mL), to help make sure you measure the right amount. See the Patient Instructions for Use at the end of this Medication Guide for information about how to measure your dose the right way. Ask your healthcare provider or pharmacist if you are not sure what dose of Oxycodone Hydrochloride Oral Solution you should take or if you are not sure how to use the oral syringe.
- **Do not stop taking Oxycodone Hydrochloride Oral Solution suddenly.** If you have been taking Oxycodone Hydrochloride Oral Solution for more than a few weeks, stopping it suddenly can make you sick with withdrawal symptoms (for example, nausea, vomiting, diarrhea, anxiety, and shivering). If your healthcare provider decides you no longer need Oxycodone Hydrochloride Oral Solution, ask how to slowly reduce this medicine. Do not stop taking Oxycodone Hydrochloride Oral Solution without talking to your healthcare provider.
- If you take more Oxycodone than prescribed, or overdose, call your local emergency number (such as 911) or your local Poison Control Center right away or get emergency help.
- Talk with your healthcare provider regularly about your pain to see if you still need to take Oxycodone.

What should I avoid while taking Oxycodone Hydrochloride Oral Solution?

- **You should not drink alcohol while using Oxycodone Hydrochloride Oral Solution. Drinking alcohol with Oxycodone Hydrochloride Oral Solution may increase your risk of having dangerous side effects or death.**
- **Do not drive, operate heavy machinery, or do other dangerous activities,** especially when you start taking Oxycodone Hydrochloride Oral Solution and when your dose is changed, until you know how Oxycodone Hydrochloride Oral Solution affects you.

Oxycodone can make you sleepy. Ask your healthcare provider to tell you when it is okay to do these activities.

What are the possible side effects of Oxycodone Hydrochloride Oral Solution?

Oxycodone Hydrochloride Oral Solution can cause serious side effects, including:

- **See “What is the most important information I should now about Oxycodone Hydrochloride Oral Solution?”**
- **Oxycodone can cause serious breathing problems that can become life-threatening, especially if Oxycodone Hydrochloride Oral Solution is used the wrong way. Call your healthcare provider or get help right away if:**
 - your breathing slows down
 - you have shallow breathing (little chest movement with breathing)
 - you feel faint, dizzy, confused, or
 - you have any other unusual symptoms

These can be symptoms that you have taken too much Oxycodone Hydrochloride Oral Solution (overdose) or the dose is too high for you. **These symptoms may lead to serious problems or death if not treated right away.**

- **Oxycodone Hydrochloride Oral Solution can cause your blood pressure to drop.** This can make you feel dizzy if you get up too fast from sitting or lying down. Low blood pressure is also more likely to happen if you take other medicines that can also lower your blood pressure. Severe low blood pressure can happen if you lose blood or take certain other medicines.
- **Oxycodone can cause physical dependence.** Do not stop taking Oxycodone or any other opioid without talking to your healthcare provider about how to slowly stop your medicine. You could become sick with uncomfortable withdrawal symptoms because your body has become used to these medicines. Physical dependence is not the same as drug addiction. Tell your healthcare provider if you have any of these symptoms of withdrawal while slowly stopping Oxycodone:

feel restless
tearing eyes
sweating
chills or hair on your arms “stand up”
muscle aches, backache
dilated pupils of your eyes
feel irritable or anxious
trouble sleeping

runny nose
yawning
nausea, loss of appetite, vomiting,
diarrhea, stomach-area
(abdominal) cramps
increase in your blood pressure,
breathing faster, or your heart
beats faster

- **There is a chance of abuse or addiction with Oxycodone Hydrochloride Oral Solution.** The chance is higher if you are or have been addicted to or abused other medicines, street drugs, or alcohol, or if you have a history of mental problems.
- **Seizures. Oxycodone Hydrochloride Oral Solution may cause seizures or make seizures that you already have worse.**

Call your healthcare provider if you have any of the symptoms listed above.

Common side effects of Oxycodone Hydrochloride Oral Solution include:

- nausea
- constipation
- vomiting
- headache
- itchiness
- trouble sleeping
- dizziness
- weakness
- drowsiness
- sweating
- lightheadedness

Constipation (not often enough or hard bowel movements) is a very common side effect of pain medicines (opioids) including Oxycodone Hydrochloride Oral Solution. Talk to your healthcare provider about dietary changes, and the use of laxatives (medicines to treat constipation) and stool softeners to prevent or treat constipation while taking Oxycodone Hydrochloride Oral Solution.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of Oxycodone Hydrochloride Oral Solution. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Oxycodone Hydrochloride Oral Solution?

- Store Oxycodone Hydrochloride Oral Solution in a dry area at room temperature 59°F to 86°F (15°C to 30°C)
- Protect Oxycodone Hydrochloride Oral Solution from moisture and light.
- After you stop taking Oxycodone, flush the unused oral solution down the toilet.

Keep Oxycodone Hydrochloride Oral Solution out of the reach of children. Accidental overdose by a child is a medical emergency and can lead to death.

General information about Oxycodone Hydrochloride Oral Solution

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Oxycodone Hydrochloride Oral Solution for a condition for which it was not prescribed.

Do not give your Oxycodone Hydrochloride Oral Solution to other people, even if they have the same symptoms you have. Selling or giving away Oxycodone Hydrochloride Oral Solution may harm others, may cause death, and is against the law.

This Medication Guide summarizes the most important information about Oxycodone Hydrochloride Oral Solution. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about Oxycodone Hydrochloride Oral Solution that is written for healthcare professionals.

For more information about Oxycodone Hydrochloride Oral Solution, go to www.lvtechinc.com or call Pharm-Olam at 1-866-511-6754.

What are the ingredients in Oxycodone Hydrochloride Oral Solution?

Active ingredient: oxycodone hydrochloride

Inactive ingredients: citric acid anhydrous, D&C Yellow #10, natural/artificial berry flavor, purified water, sodium citrate dihydrate, sodium benzoate, saccharin sodium, and sorbitol,.

Lehigh Valley Technologies, Inc.
Allentown, PA
Draft 2010

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

Patient Instructions for Use

Oxycodone Hydrochloride Oral Solution 100 mg per 5 mL (20 mg per mL) Oral Syringe

Important information about measuring Oxycodone Hydrochloride Oral Solution

- **Always use the oral syringe provided with your Oxycodone Hydrochloride Oral Solution to make sure you measure the right amount.**
- **Measure the dose of medicine from the widest part of the plunger. Do not measure from the narrow tip. See Figure 1.**

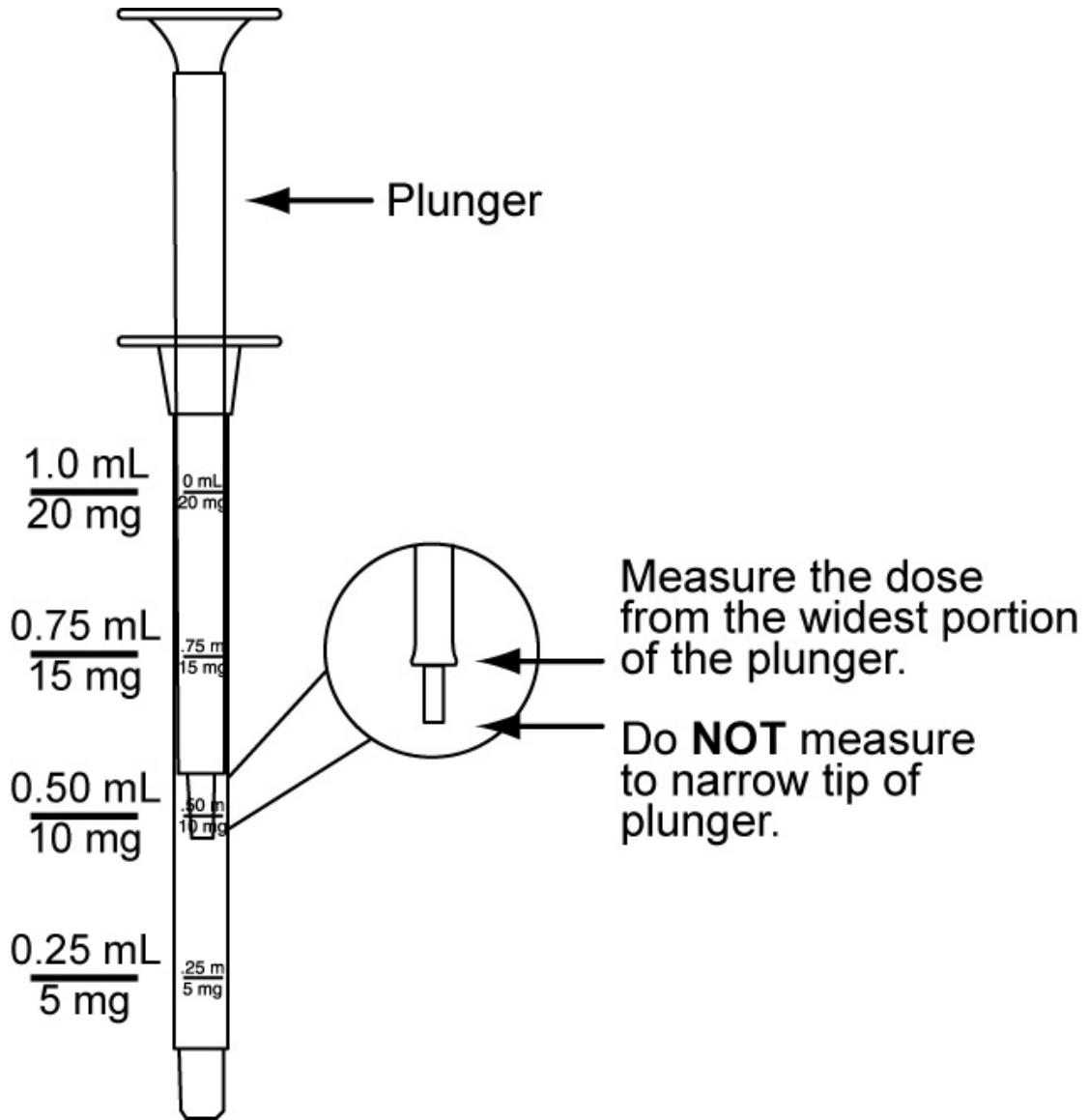
Step 1. Insert the tip of the oral syringe into the medicine bottle.

Step 2. Pull back the plunger to the line that matches the dose prescribed by your healthcare provider.

Step 3. Remove the oral syringe from the medicine bottle.

Step 4. Take your medicine by slowly pushing the plunger until the oral syringe is empty.

Figure 1



REMS

NDA 200535 Oxycodone Hydrochloride Oral Solution (20 mg/mL)

Class of Product: Opioid Agonist

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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL:

The goal of this REMS is to inform patients about the serious risks associated with the use of Oxycodone Hydrochloride Oral Solution.

II. REMS ELEMENTS:

A. Medication Guide

Lehigh Valley Technologies, Inc. (LVT) will ensure that a currently approved Medication Guide will be dispensed with each Oxycodone Hydrochloride Oral Solution prescription in accordance with 21 CFR 208.24.

B. Timetable for Submission of Assessments

LVT will submit REMS Assessments to the FDA at, 18 months, 3 years, and 7 years from the date of approval of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. LVT will submit each assessment so that it will be received by the FDA on or before the due date.