

MEDICATION GUIDE

DOLOPHINE® (DOL-o-feen) (methadone hydrochloride) tablets, CII

DOLOPHINE is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage pain severe enough to require daily around-the-clock, long-term treatment with an opioid, when other pain treatments such as non-opioid pain medicines or immediate-release opioid medicines do not treat your pain well enough or you cannot tolerate them.
- A long-acting 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 than can lead to death.
- Not for use to treat pain that is not around-the-clock.
- Also used to manage drug addiction.

Important information about DOLOPHINE:

- **Get emergency help right away if you take too much DOLOPHINE (overdose).** When you first start taking DOLOPHINE, 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.
- Never give anyone your DOLOPHINE. They could die from taking it. Store DOLOPHINE away from children and in a safe place to prevent stealing or abuse. Selling or giving away DOLOPHINE is against the law.

Do not take DOLOPHINE if you have:

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

Before taking DOLOPHINE, tell your healthcare provider if you have a history of:

- head injury, seizures
- liver, kidney, thyroid problems
- problems urinating
- heart rhythm problems (Long QT syndrome)
- 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 DOLOPHINE during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **breastfeeding.** DOLOPHINE passes into breast milk and may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking DOLOPHINE with certain other medicines may cause serious side effects.

When taking DOLOPHINE:

- Do not change your dose. Take DOLOPHINE exactly as prescribed by your healthcare provider.
- Do not take more than your prescribed dose in 24 hours. If you take DOLOPHINE for pain and miss a dose, take DOLOPHINE as soon as possible and then take your next dose 8 or 12 hours later as directed by your healthcare provider. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule.
- If you take DOLOPHINE for opioid addiction and miss a dose, take your next dose the following day as scheduled. Do not take extra doses. Taking more than the prescribed dose may cause you to overdose because DOLOPHINE builds up in your body over time.
- Do not crush, dissolve, snort or inject DOLOPHINE because this may cause you to overdose and die.
- **Call your healthcare provider if the dose you are taking does not control your pain.**
- **Do not stop taking DOLOPHINE without talking to your healthcare provider.**
- After you stop taking DOLOPHINE, flush any unused tablets down the toilet.

While taking DOLOPHINE DO NOT:

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

The possible side effects of DOLOPHINE 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, or you are feeling faint.

These are not all the possible side effects of DOLOPHINE. 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.**

Manufactured by: Roxane Laboratories, Inc., Columbus, Ohio 43216, www.Roxane.com, or call 1-800-962-8364