

MEDICATION GUIDE

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

DOLOPHINE Tablets are:

- 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 Tablets:

- **Get emergency help right away if you take too much DOLOPHINE Tablets (overdose).** When you first start taking DOLOPHINE Tablets, 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 DOLOPHINE Tablets 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 your DOLOPHINE Tablets. They could die from taking it. Store DOLOPHINE Tablets away from children and in a safe place to prevent stealing or abuse. Selling or giving away DOLOPHINE Tablets is against the law.

Do not take DOLOPHINE Tablets 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 Tablets, 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 plan to become pregnant.** If you take DOLOPHINE Tablets while pregnant, your baby may have symptoms of opioid withdrawal or respiratory depression at birth. Talk to your doctor if you are pregnant or plan to become pregnant.
- **breastfeeding.** DOLOPHINE Tablets passes into breast milk and may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking DOLOPHINE Tablets with certain other medicines may cause serious side effects.

When taking DOLOPHINE Tablets:

- Do not change your dose. Take DOLOPHINE Tablets exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- Do not take more than your prescribed dose in 24 hours. If you take DOLOPHINE Tablets for pain and miss a dose, take DOLOPHINE Tablets 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 Tablets 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 Tablets builds up in your body over time.
- Do not crush, dissolve, snort or inject DOLOPHINE Tablets 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 Tablets without talking to your healthcare provider.**
- After you stop taking DOLOPHINE Tablets, flush any unused Tablets down the toilet.

While taking DOLOPHINE Tablets DO NOT:

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

The possible side effects of DOLOPHINE Tablets 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 DOLOPHINE Tablets. 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.**

Distr. by: **West-Ward Pharmaceuticals Corp.**, Eatontown, NJ 07724, For information, please call 1-800-962-8364.

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

Revised: December 2016