

PATIENT INFORMATION
DOLOPHINE® HYDROCHLORIDE CII
(Methadone Hydrochloride Tablets), 5 mg and 10 mg

WARNINGS:

Keep DOLOPHINE out of the reach of children. Accidental overdose by a child is a medical emergency and can result in death. If a child accidentally takes DOLOPHINE, get emergency help right away.

Do not take a higher dose of DOLOPHINE or take it more often than prescribed. This can lead to an overdose and possible death.

Read the Patient Information that comes with DOLOPHINE before you take it and each time you get a new prescription. There may be new information. This leaflet does not take the place of talking with your doctor about your medical condition or your treatment. Share the important information in this leaflet with members of your household.

What Is The Most Important Information I Should Know About DOLOPHINE?

- **DOLOPHINE can cause life threatening breathing problems** which can lead to death. These problems are more likely to happen when DOLOPHINE is first started or in someone who is not already taking other narcotic (opioid) pain medicines.
 - **Breathing problems from DOLOPHINE may not happen right away after taking a dose. Sometimes breathing problems will happen a while after you take a dose, even after pain has returned. It is very important that you take DOLOPHINE exactly as your doctor has prescribed. Talk to your doctor about your pain. Your doctor can decide if your DOLOPHINE dose needs to be changed.**
- **DOLOPHINE can cause life-threatening heart beat problems that can lead to death.** Most heart beat problems have happened in people using large doses of DOLOPHINE for pain treatment. Some heart beat problems have happened in people using smaller doses of DOLOPHINE for treatment of narcotic drug addiction.

What is DOLOPHINE?

DOLOPHINE is a prescription medicine that contains methadone, which is a narcotic pain medicine similar to morphine. **DOLOPHINE 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 and misuse. Keep your DOLOPHINE tablets in a safe place** to protect them from theft. Never give DOLOPHINE to anyone else even if they have the same symptoms you have. It may harm them and even cause death. **Selling or giving away this medicine is dangerous and against the law.**

DOLOPHINE is used:

1. to treat moderate to severe pain in people that do not respond to non-narcotic pain medicines;
2. to control withdrawal symptoms in patients being treated for narcotic drug addiction;
3. for maintenance treatment of narcotic drug addiction along with other social and medical services. Stopping maintenance treatment of narcotic drug addiction with DOLOPHINE may result in a return to narcotic drug use.

Who Should Not Take DOLOPHINE?

Do not take DOLOPHINE if you:

- have severe asthma or severe lung problems.
- have a blockage or obstruction in your intestines.
- are allergic to methadone or anything else in DOLOPHINE. See the end of this leaflet for a complete list of ingredients.

What Should I Tell my Doctor Before I Start Taking DOLOPHINE?

DOLOPHINE may not be right for you. Before starting DOLOPHINE, tell your doctor about all your medical and mental conditions including a history of drug or alcohol abuse or addiction.

Tell your doctor if you:

- **are pregnant or plan to become pregnant.** DOLOPHINE may harm your unborn baby.
- **are breast feeding.** DOLOPHINE passes through your breast milk and may harm your baby. You should choose to use DOLOPHINE or breastfeed, but not both.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicines may cause serious or life-threatening medical problems when taken with DOLOPHINE. **Be especially careful about other medicines that may make you sleepy, such as other pain medicines, anti-depressant medicines, sleeping pills, anxiety medicines, antihistamines, or tranquilizers.** Sometimes, the doses of certain medicines (including DOLOPHINE) may need to be changed if they are used together.

Do not take any medicine while using DOLOPHINE until you have first talked to your doctor or pharmacist. They will be able to tell you if it is safe to take other medicines while you are using DOLOPHINE.

Know the medicines you take. Keep a list of your medicines and show it to your doctor and pharmacist each time you get a new medicine.

How Should I Take DOLOPHINE?

- **Take DOLOPHINE exactly as prescribed. Follow your doctor's directions exactly.** Your doctor may change your dose based on your reactions to the medicine. Do not change your dose unless your doctor tells you to change it. **Do not take a higher dose of DOLOPHINE or take it more often than prescribed. This can lead to an overdose and possibly death.**
- **If you take too much DOLOPHINE or overdose**, call 911 or your local emergency number right away.
- Review your medical conditions regularly with your doctor to determine if you still need DOLOPHINE, or if the dose needs to be adjusted.
- When starting treatment with DOLOPHINE for narcotic drug dependence, you should be aware that your dose of methadone will "hold" for longer periods of time as treatment goes on.

- **Stopping DOLOPHINE.** Ask your doctor for instructions on how to stop this medicine slowly to avoid uncomfortable symptoms. You should not stop taking DOLOPHINE all at once if you have been taking it for more than a few days.
- Tell all health professionals that treat you that you take DOLOPHINE.
- After stopping treatment with DOLOPHINE, flush the unused tablets down the toilet.

What Should I Avoid While Taking DOLOPHINE?

- **Do not drive, operate heavy machinery, or do other possible dangerous activities** until you know how DOLOPHINE affects you. DOLOPHINE can make you sleepy. Ask your doctor when it is okay to do these activities.
- **Do not drink alcohol while using DOLOPHINE.** It may increase the chance of having dangerous side effects.
- **Do not take other medicines with DOLOPHINE without first talking with your doctor.**

What are the Possible Side Effects of DOLOPHINE?

- **DOLOPHINE can cause life threatening breathing and heart problems which can lead to death** See “What Is The Most Important Information I Should Know About DOLOPHINE?”
 - **Call your doctor or get medical help right away if you:**
 - have trouble breathing
 - have extreme drowsiness and breathing slows down
 - have slow shallow breathing (little chest movement with breathing)
 - fast or slowed heartbeat
 - feel faint, very dizzy, confused, have palpitations (irregular heart beat) or any other unusual symptoms

These can be symptoms that you have taken too much (overdose of) DOLOPHINE, or the dose is too high for you. They can also be symptoms of a serious heart reaction.

These symptoms can lead to serious problems or death if not treated right away.

- **DOLOPHINE can cause your blood pressure to drop.** This can make you feel dizzy if you get up too fast from sitting or lying down.
- **DOLOPHINE can cause physical dependence.** Do not stop taking DOLOPHINE or any other opioid without first talking to your doctor. You could become sick with uncomfortable withdrawal symptoms because your body has become used to these medicines. Talk to your doctor about slowly stopping DOLOPHINE to avoid getting sick with withdrawal symptoms. Physical dependency is not the same as drug addiction.
- **For patients using DOLOPHINE for pain treatment, there is a chance of abuse or addiction with DOLOPHINE.** 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.

Some common side effects of DOLOPHINE are lightheadedness, dizziness, drowsiness, nausea, vomiting and sweating. Other side effects include weakness, headache, constipation, itching, and dry mouth.

Talk to your doctor about any side effects that bother you or that do not go away.

These are not all the possible side effects of DOLOPHINE. For a complete list, ask your doctor or pharmacist.

How Should I Store DOLOPHINE Tablets?

- **Keep DOLOPHINE in a safe place away from children. Accidental use by a child is a medical emergency that can result in death. If a child accidentally takes DOLOPHINE, get emergency help right away.**
- Keep DOLOPHINE at room temperature, 59 to 86°F (15 to 30°C).
- Always keep DOLOPHINE in a secure place to protect from theft.
- Dispose of any unused DOLOPHINE remaining from a prescription as soon as they are no longer needed. Unused tablets should be flushed down the toilet.

General Information About DOLOPHINE.

Medicines are sometimes prescribed for purposes other than those listed in patient information leaflet. Do not use DOLOPHINE for a condition for which it was not prescribed. **Do not give DOLOPHINE to other people, even if they have the same symptoms you have. DOLOPHINE can harm other people and even cause death. Sharing DOLOPHINE is against the law.**

This leaflet summarizes the most important information about DOLOPHINE. If you would like more information, talk with your doctor. You can also ask your pharmacist or doctor for information about DOLOPHINE that is written for healthcare professionals, or you can visit www.Roxane.com or call 1-800-962-8364.

What are the Ingredients in DOLOPHINE?

Active Ingredient: methadone hydrochloride, USP

Inactive Ingredients: magnesium stearate, microcrystalline cellulose, and starch.