Medication Guide Levorphanol Tartrate (lee vor' fa nol tar' trate) Tablets USP, CII

Levorphanol tartrate tablets are:

- 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 non-opioid 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 levorphanol tartrate tablets:

- Get emergency help right away if you take too much levorphanol tartrate tablets (overdose). When you first start taking levorphanol tartrate 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 levorphanol tartrate 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 else your levorphanol tartrate tablets. They could die from taking it. Selling or giving away levorphanol tartrate tablets is against the law.
- Store levorphanol tartrate tablets securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

Do not take levorphanol tartrate tablets if you have:

- severe asthma trouble breathing, or other lung problems
- a bowel blockage or have narrowing of the stomach or intestines.
- previously had an allergic reaction to levorphanol.

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

When taking levorphanol tartrate tablets:

- Do not change your dose. Take levorphanol tartrate tablets exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- Take your prescribed dose every 6 to 8 hours as needed for pain. 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 levorphanol tartrate tablets regularly, do not stop taking without talking to your healthcare provider.
- Dispose of expired, unwanted, or unused levorphanol tartrate tablets by promptly flushing down the toilet if a drug take-back option is not readily available. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

While taking levorphanol tartrate tablets DO NOT:

- Drive or operate heavy machinery, until you know how levorphanol tartrate tablets affects you. Levorphanol tartrate 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 levorphanol tartrate tablets may cause
 you to overdose and die.

The possible side effects of levorphanol tartrate tablets:

• 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 levorphanol tartrate 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.**

Manufactured by: Ohm Laboratories Inc. New Brunswick, NJ Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512 call 1-800-406-7984

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

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