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2. Levo-Dromoran

Levo-Dromoran (Oral)

Generic name: levorphanol [lee-VOR-fa-nol]

Drug class: Opioids (narcotic analgesics)

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Uses Before taking Dosage Warnings Side effects Brand names



The Levo-Dromoran brand name has been **discontinued** in the U.S. If generic versions of this product have been approved by the FDA, there may be generic equivalents available.

Oral route(Tablet)

Addiction, Abuse, and Misuse:

Levorphanol tartrate tablets expose patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing levorphanol tartrate tablets, and monitor all patients regularly for the development of these behaviors or conditions.

Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS) To ensure that the benefits of opioid analgesics outweigh the risks of addiction, abuse, and misuse, the Food and Drug Administration (FDA has required a REMS for these products. Under the requirements of the REMS, drug companies with approved opioid analgesic products must make REMS-compliant education programs available to healthcare providers. Healthcare providers are strongly encouraged to complete a REMS-compliant education program, counsel patients and/or their caregivers, with every prescription, on safe use, serious risks, storage, and disposal of these products, emphasize to patients and their caregivers the importance of reading the Medication Guide every time it is provided by their pharmacist, and consider other tools to improve patient, household, and community safety.

Life-Threatening Respiratory Depression:

Serious, life-threatening, or fatal respiratory depression may occur with use of levorphanol tartrate tablets. Monitor for respiratory depression, especially during initiation of levorphanol tartrate tablets or following a dose increase.

Accidental Ingestion:

Accidental ingestion of even one dose of levorphanol tartrate tablets, especially by children, can result in a fatal overdose of levorphanol tartrate tablets.

Neonatal Opioid Withdrawal Syndrome:

Prolonged use of levorphanol tartrate tablets during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

Risks from Concomitant Use with Benzodiazepines or Other CNS Depressants:

Concomitant use of opioids with benzodiazepines or other CNS depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of levorphanol tartrate tablets and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate. Limit dosages and durations to the minimum required. Follow patients for signs and symptoms of respiratory depression and sedation .

Uses for Levo-Dromoran

Levorphanol is used to relieve pain severe enough to require opioid treatment and when other pain medicines did not work well enough or cannot be tolerated. It belongs to the group of medicines called narcotic analgesics (pain medicines). It acts on the central nervous system (CNS) to relieve pain.

When levorphanol is used for a long time, it may become habit-forming, causing mental or physical dependence. However, people who have continuing pain should not let the fear of dependence keep them from using narcotics to relieve their pain. Mental dependence (addiction) is not likely to occur when narcotics are used for this purpose. Physical dependence may lead to withdrawal side effects if treatment is stopped suddenly. However, severe withdrawal side effects can usually be prevented by gradually reducing the dose over a period of time before treatment is stopped completely.

This medicine is available only under a restricted distribution program called the Opioid Analgesic REMS (Risk Evaluation and Mitigation Strategy) program.

Before using Levo-Dromoran

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For this medicine, the following should be considered:

Allergies

Tell your doctor if you have ever had any unusual or allergic reaction to this medicine or any other medicines. Also tell your health care professional if you have any other types of allergies, such as to foods, dyes, preservatives, or animals. For non-prescription products, read the label or package ingredients carefully.

Pediatric

Appropriate studies have not been performed on the relationship of age to the effects of levorphanol in the pediatric population. Safety and efficacy have not been established.

Geriatric

Appropriate studies performed to date have not demonstrated geriatric-specific problems that would limit the usefulness of levorphanol in the elderly. However, elderly patients are more likely to have age-related liver, kidney, heart, or lung problems, which may require caution and an adjustment in the dose for patients receiving levorphanol.

Breast Feeding

There are no adequate studies in women for determining infant risk when using this medication during breastfeeding. Weigh the potential benefits against the potential risks before taking this medication while breastfeeding.

Interactions with Medicines

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. When you are taking this medicine, it is especially important that your healthcare professional know if you are taking any of the medicines listed below. The following interactions have been selected on the basis of their potential significance and are not necessarily all-inclusive.

Using this medicine with any of the following medicines is not recommended. Your doctor may decide not to treat you with this medication or change some of the other medicines you take.

- Nalmefene
- Naltrexone
- Safinamide
- Samidorphan

Using this medicine with any of the following medicines is usually not recommended, but may be required in some cases. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

- Acepromazine
- Alfentanil
- Almotriptan
- Alprazolam
- Amifampridine
- Amineptine
- Amitriptyline
- Amitriptylinoxide
- Amobarbital
- Amoxapine
- Amphetamine
- Anileridine
- Aripiprazole
- Asenapine

- BaclofenBenperidolBenzhydro
- Benzhydrocodone
- Benzphetamine
- Bromazepam
- Bromopride
- Brompheniramine
- Buprenorphine
- Bupropion
- Buspirone
- Butabarbital
- Butorphanol
- Calcium Oxybate
- Cannabidiol
- Cannabis
- Carbamazepine
- Carbinoxamine
- Carisoprodol
- Carphenazine
- Cetirizine
- Chloral Hydrate
- Chlordiazepoxide
- Chlorpheniramine
- Chlorpromazine
- Chlorzoxazone
- Citalopram
- Clobazam
- Clomipramine
- Clonazepam
- Clopidogrel
- Clorazepate
- Clozapine
- Cocaine
- Codeine

- CyclobenzaprineDaridorexant
- Desipramine
- Desmopressin
- Desvenlafaxine
- Dexmedetomidine
- Dextroamphetamine
- Dextromethorphan
- Dezocine
- Diazepam
- Dibenzepin
- Dichloralphenazone
- Difenoxin
- Dihydrocodeine
- Diphenhydramine
- Diphenoxylate
- Dolasetron
- Donepezil
- Doxepin
- Doxylamine
- Droperidol
- Duloxetine
- Eletriptan
- Enflurane
- Escitalopram
- Esketamine
- Estazolam
- Eszopiclone
- Ethchlorvynol
- Ethopropazine
- Ethylmorphine
- Fenfluramine
- Fentanyl

- Flibanserin • Fluoxetine • Fluphenazine • Flurazepam
- Fluspirilene
- Fluvoxamine
- Fospropofol
- Frovatriptan
- Furazolidone
- Gabapentin
- Gabapentin Enacarbil
- Gepirone
- Granisetron
- Halazepam
- Haloperidol
- Halothane
- Hexobarbital
- Hydrocodone
- Hydromorphone
- Hydroxytryptophan
- Hydroxyzine
- Imipramine
- Iproniazid
- Isocarboxazid
- Isoflurane
- Ketamine
- Ketazolam
- Ketobemidone
- Lacosamide
- Lasmiditan
- Lemborexant
- Levocetirizine
- Levomilnacipran
- Linezolid

- LisdexamfetamineLithiumLofepramineLofexidine
- Lorazepam
- Lorcaserin
- Loxapine
- Magnesium Oxybate
- Meclizine
- Melitracen
- Melperone
- Meperidine
- Mephobarbital
- Meprobamate
- Meptazinol
- Mesoridazine
- Metaxalone
- Methadone
- Methamphetamine
- Methdilazine
- Methocarbamol
- Methohexital
- Methotrimeprazine
- Methylene Blue
- Metoclopramide
- Midazolam
- Milnacipran
- Mirtazapine
- Moclobemide
- Molindone
- Moricizine
- Morphine
- Morphine Sulfate Liposome

- Nalbuphine • Naratriptan Nefazodone Nialamide
- Nicomorphine
- Nitrazepam
- Nitrous Oxide
- Nortriptyline
- Olanzapine
- Ondansetron
- Opipramol
- Opium
- Opium Alkaloids
- Orphenadrine
- Oxazepam
- Oxycodone
- Oxymorphone
- Ozanimod
- Palonosetron
- Papaveretum
- Paregoric
- Paroxetine
- Pentazocine
- Pentobarbital
- Perampanel
- Perazine
- Periciazine
- Perphenazine
- Phenelzine
- Phenobarbital
- Pimozide
- Piperacetazine
- Pipotiazine
- Piritramide

Potassium Oxybate
Prazepam
Pregabalin
Primidone
Procarbazine
Prochlorperazine
Promazine
Promethazine
Propofol
Protriptyline
Quazepam
Quetiapine
Ramelteon

Rasagiline

Remifentanil

Remimazolam

• Ropeginterferon Alfa-2b-njft

Rizatriptan

Scopolamine

Secobarbital

• Selegiline

Sertindole

Sertraline

Sibutramine

Sodium Oxybate

St John's Wort

• Sufentanil

• Sulpiride

Sumatriptan

Suvorexant

Temazepam

• Thiethylperazine

• Tapentadol

 Thiopental • Thiopropazate Thioridazine Tianeptine Tilidine Tizanidine Tolonium Chloride Topiramate Tramadol Tranylcypromine Trazodone Triazolam • Trifluoperazine • Trifluperidol • Triflupromazine Trimeprazine • Trimipramine • Tryptophan Venlafaxine Vilazodone Vortioxetine Zaleplon • Ziprasidone • Zolmitriptan • Zolpidem • Zopiclone • Zotepine Zuranolone

Using this medicine with any of the following medicines may cause an increased risk of certain side effects, but using both drugs may be the best treatment for you. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

Risperidone

Interactions with Food/Tobacco/Alcohol

Certain medicines should not be used at or around the time of eating food or eating certain types of food since interactions may occur. Using alcohol or tobacco with certain medicines may also cause interactions to occur. The following interactions have been selected on the basis of their potential significance and are not necessarily all-inclusive.

Using this medicine with any of the following is usually not recommended, but may be unavoidable in some cases. If used together, your doctor may change the dose or how often you use this medicine, or give you special instructions about the use of food, alcohol, or tobacco.

Ethanol

Other Medical Problems

The presence of other medical problems may affect the use of this medicine. Make sure you tell your doctor if you have any other medical problems, especially:

- Addison's disease (adrenal gland problem) or
- · Alcohol abuse, history of or
- · Brain tumor or
- Breathing or lung problems (eg, chronic obstructive pulmonary disease [COPD], hypoxia) or
- · Congestive heart failure or
- Cor pulmonale (serious heart condition) or
- Drug dependence, especially narcotic abuse or dependence, or history of or
- Enlarged prostate (BPH, prostatic hypertrophy) or
- · Gallbladder problems or
- · Head injuries or
- · Hypothyroidism (an underactive thyroid) or
- · Increased pressure in your head or
- · Infection, severe or
- · Mental illness, history of or
- · Problems with passing urine or
- Stomach or bowel problems—Use with caution. May increase risk for more serious side effects.
- · Gallbladder surgery or
- Lung or breathing problems (eg, asthma, respiratory depression), severe or
- Stomach or bowel blockage (eg, paralytic ileus), known or suspected—Should not be used in patients with these conditions.
- · Heart disease or
- Hypotension (low blood pressure) or
- · Myocardial infarction (heart attack) or
- Pancreatitis (swelling of the pancreas) or

- Seizures, history of—Use with caution. May make these conditions worse.
- · Kidney disease or
- Liver disease—Use with caution. The effects may be increased because of slower removal of the medicine from the body.

Proper use of Levo-Dromoran

Take this medicine only as directed by your doctor. Do not take more of it, do not take it more often, and do not take it for a longer time than your doctor ordered. This is especially important for elderly patients, who may be more sensitive to the effects of pain medicines. If too much of this medicine is taken for a long time, it may become habit-forming (causing mental or physical dependence) or cause an overdose.

It is very important that you understand the rules of the Opioid Analgesic REMS program to prevent addiction, abuse, and misuse of levorphanol. This medicine should also come with a Medication Guide. Read and follow these instructions carefully. Read it again each time you refill your prescription in case there is new information. Ask your doctor if you have any questions.

Dosing

The dose of this medicine will be different for different patients. Follow your doctor's orders or the directions on the label. The following information includes only the average doses of this medicine. If your dose is different, do not change it unless your doctor tells you to do so.

The amount of medicine that you take depends on the strength of the medicine. Also, the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are using the medicine.

- For oral dosage form (tablets):
 - For moderate to severe pain:
 - Adults—At first, 1 to 2 milligrams (mg) every 6 to 8 hours as needed. Your doctor may increase your dose as needed. However, the dose is usually not more than 6 to 12 mg per day.
 - Children—Use and dose must be determined by your doctor.

Missed Dose

If you miss a dose of this medicine, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

Storage

Store the medicine in a closed container at room temperature, away from heat, moisture, and direct light. Keep from freezing.

Keep out of the reach of children.

Do not keep outdated medicine or medicine no longer needed.

Ask your healthcare professional how you should dispose of any medicine you do not use.

Levorphanol can cause serious unwanted effects or fatal overdose if taken by children, pets, or adults who are not used to strong narcotic pain medicines. Make sure you store the medicine in a safe and secure place to prevent others from getting it.

Do not throw unused medicine in the trash. Flush unused tablets down the toilet.

Detailed Levo-Dromoran dosage information

Precautions while using Levo-Dromoran

It is very important that your doctor check your progress while you are using this medicine, especially within the first 24 to 72 hours of treatment. This will allow your doctor to see if the medicine is working properly and to decide if you should continue to take it. Blood and urine tests may be needed to check for unwanted effects.

This medicine may cause a serious type of allergic reaction called anaphylaxis, which can be life-threatening and requires immediate medical attention. Call your doctor right away if you have a rash, itching, hoarseness, trouble breathing, trouble swallowing, or any swelling of your hands, face, or mouth while you are using this medicine.

This medicine will add to the effects of alcohol and other CNS depressants. CNS depressants are medicines that slow down the nervous system, which may cause drowsiness or make you less alert. Some examples of CNS depressants are antihistamines or medicine for allergies or colds, sedatives, tranquilizers, or sleeping medicine, other prescription pain medicine or narcotics, medicine for seizures or barbiturates, muscle relaxants, or anesthetics, including some dental anesthetics. Check with your doctor before taking any of these medicines while you are using this medicine.

This medicine may be habit-forming. If you feel that the medicine is not working as well, do not use more than your prescribed dose. Call your doctor for instructions.

If you think you or someone else may have taken an overdose of this medicine, get emergency help at once. Signs of an overdose include: dark urine, difficult or troubled breathing, irregular, fast or slow, or shallow breathing, nausea or vomiting, pain in the upper stomach, pale or blue lips, fingernails, or skin, pinpoint pupils of the eyes, or yellow eyes or skin.

Dizziness, lightheadedness, or fainting may occur when you get up suddenly from a lying or sitting position. Getting up slowly may help lessen this problem. Also, lying down for a while may relieve dizziness or lightheadedness.

This medicine may make you dizzy, drowsy, or lightheaded. Do not drive or do anything else that could be dangerous until you know how this medicine affects you.

Do not change your dose or suddenly stop using this medicine without first checking with your doctor. Your doctor may want you to gradually reduce the amount you are using before stopping it completely. This may help prevent worsening of your condition and reduce the possibility of withdrawal symptoms, such as abdominal or stomach cramps, anxiety, fever, nausea, runny nose, sweating, tremors, or trouble with sleeping.

Using this medicine while you are pregnant may cause neonatal withdrawal syndrome in your newborn baby. Tell your doctor right away if your child has the following symptoms: abnormal sleep pattern, diarrhea, high-pitched cry, irritability, shakiness or tremor, weight loss, vomiting, or failure to gain weight.

Using too much of this medicine may cause infertility (unable to have children). Talk with your doctor before using this medicine if you plan to have children.

Check with your doctor right away if you have anxiety, restlessness, a fast heartbeat, fever, sweating, muscle spasms,

twitching, nausea, vomiting, diarrhea, or see or hear things that are not there. These may be symptoms of a serious condition called serotonin syndrome. Your risk may be higher if you also take certain other medicines that affect serotonin levels in your body.

Using narcotics for a long time can cause severe constipation. To prevent this, your doctor may direct you to take laxatives, drink a lot of fluids, or increase the amount of fiber in your diet. Be sure to follow the directions carefully, because continuing constipation can lead to more serious problems.

Do not take other medicines unless they have been discussed with your doctor. This includes prescription or nonprescription (over-the-counter [OTC]) medicines and herbal or vitamin supplements.

Side Effects of Levo-Dromoran

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur:

Incidence not known

- Agitation
- · attempts at killing oneself
- bluish lips or skin
- blurred vision
- change in consciousness
- · cold, clammy skin
- confusion
- · darkening of the skin
- · decrease in the frequency of urination
- · decreased awareness or responsiveness
- · decreased urine output
- depression
- diarrhea
- · difficulty in passing urine (dribbling)
- · difficulty swallowing
- · dizziness, faintness, or lightheadedness when getting up suddenly from a lying or sitting position
- extra heartbeat
- · extremely shallow or slow breathing
- · fast, slow, irregular, pounding, or racing heartbeat or pulse
- · fast, weak pulse

- fever
- hostility
- · hives or welts, itching, skin rash
- lightheadedness
- · loss of appetite
- loss of consciousness
- muscle twitching
- nausea
- no blood pressure or pulse
- · not breathing
- overactive reflexes
- · painful urination
- poor coordination
- puffiness or swelling of the eyelids or around the eyes, face, lips, or tongue
- · rapid weight gain
- · restlessness
- seizures
- · severe sleepiness
- shivering
- · stopping of the heart
- sweating
- · swelling of the face, ankles, or hands
- talking or acting with excitement you cannot control
- tightness in the chest
- · trembling or shaking
- twitching
- · unusual drowsiness, dullness, tiredness, weakness or feeling of sluggishness
- vomiting

Get emergency help immediately if any of the following symptoms of overdose occur:

Symptoms of overdose

- · Chest pain or discomfort
- constricted, pinpoint, or small pupils (black part of the eye)
- decreased awareness or responsiveness

- · difficult or troubled breathing
- · difficulty with sleeping
- · dilated neck veins
- disorientation
- · drowsiness to profound loss of consciousness
- extreme tiredness or weakness
- headache
- · irregular, fast or slow, or shallow breathing
- · no muscle tone or movement
- · not breathing
- · pale or blue lips, fingernails, or skin
- · seeing, hearing, or feeling things that are not there
- · sleepiness or unusual drowsiness
- swelling of the face, fingers, feet, or lower legs
- · weight gain

Some side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects. Check with your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:

Incidence not known

- · Abnormal dreams
- absence of or decrease in body movement
- · belching
- · change in personality
- · changes in vision
- discouragement
- · double vision
- · dry mouth
- · false beliefs that cannot be changed by facts
- · feeling sad or empty
- heartburn
- · increase in body movements
- indigestion
- irritability

- · loss of interest or pleasure
- · loss of memory
- nervousness
- · poor insight and judgment
- problems with memory or speech
- · redness of the skin
- seeing double
- stomach discomfort, upset, or pain
- sweating
- · trouble concentrating
- · trouble recognizing objects
- · trouble sleeping
- · trouble thinking and planning
- trouble walking
- twitching, twisting, uncontrolled repetitive movements of the tongue, lips, face, arms, or legs
- · upper abdominal or stomach pain

Other side effects not listed may also occur in some patients. If you notice any other effects, check with your healthcare professional.

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

1 Levo-Dromoran side effects (more detail)

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Commonly used brand name(s)

In the U.S.

• Levo-Dromoran

Available Dosage Forms:

Tablet

Therapeutic Class: Analgesic

Chemical Class: Opioid

More about Levo-Dromoran (levorphanol)

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- Latest FDA alerts (1)
- Side effects
- Dosage information
- During pregnancy
- Drug class: Opioids (narcotic analgesics)

Professional resources

- Levorphanol monograph
- Levorphanol (FDA)

Related treatment guides

- Pain
- Light Sedation

Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Medical Disclaimer

DRUG STATUS

Availability

O Discontinued

Pregnancy & Lactation

্প Risk data available

CSA Schedule*

2 High potential for abuse

Approval History

□ Drug history at FDA

User Reviews & Ratings

3 Reviews

Images

Levo-Dromoran 2 mg (LEVO-DROMORAN)

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