

Medication Guide

DEMEROL® (de-meh-rol)

(meperidine hydrochloride, USP) Tablets and Oral Solution, CII

DEMEROL Tablets and Oral Solution are:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage the relief short-term (acute) pain, 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 DEMEROL Tablets and Oral Solution:

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

Do not take DEMEROL Tablets and Oral Solution if you have:

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

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

When taking DEMEROL Tablets and Oral Solution:

- Do not change your dose. Take DEMEROL Tablets and Oral Solution exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- Always use a calibrated measuring device for DEMEROL Oral Solution to correctly measure your dose. Never use a household teaspoon or tablespoon to measure DEMEROL Oral Solution.
- Mix each dose of DEMEROL oral solution into one-half glass of water before swallowing.

- Take your prescribed dose every 3 or 4 hours as necessary. 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 DEMEROL Tablets and Oral Solution regularly, do not stop taking DEMEROL Tablets and Oral Solution without talking to your healthcare provider.
- After you stop taking DEMEROL Tablets and Oral Solution, flush any unused tablets down the toilet.

While taking DEMEROL Tablets and Oral Solution DO NOT:

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

The possible side effects of DEMEROL Tablets and Oral Solution:

- 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 DEMEROL Tablets and Oral Solution. 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 for and Distributed by: Validus Pharmaceuticals LLC, Parsippany, NJ, 07054
www.validuspharma.com or call 1-866-982-5438 (1-866-9VALIDUS)

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

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