

MEDICATION GUIDE
DARVON-N[®] [dar-von-N] (C-IV)
(propoxyphene napsylate)
Tablets

DARVON[®] [dar-von](C-IV)
(propoxyphene hydrochloride capsules)
Puvules[®]

Read this Medication Guide before you start taking Darvon-N or Darvon, and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment.

What is the most important information I should know about Darvon-N and Darvon?

Darvon-N and Darvon, and other medicines that contain propoxyphene can cause serious side effects, including:

Overdoses by accident or on purpose (intentional overdose). Overdoses with Darvon-N and Darvon may happen when it is taken by itself, or with alcohol or other medicines that can also decrease your breathing and make you very sleepy.

- **Death can happen within 1 hour of taking an overdose of Darvon-N or Darvon.**
Many of the deaths that happen in people who take Darvon-N and Darvon happen in those who:
 - have emotional problems
 - have thoughts of suicide or attempted suicide, or
 - also take antidepressants, sedatives, tranquilizers, muscle relaxants, or other medicines that affect your breathing and make you very sleepy. **You should not use any of these medicines with Darvon-N or Darvon without talking to your doctor.**
- **Before taking Darvon-N or Darvon tell your doctor if you:**
 - have a lung problem, such as COPD or cor pulmonale
 - have liver or kidney problems
 - have problems with your pancreas or gallbladder
 - have a history of head injury
 - are over age 65
 - have a history of drug or alcohol abuse or addiction

Take Darvon-N and Darvon exactly as prescribed. Do not change your dose or stop taking Darvon-N or Darvon without first talking to your doctor.

- If you take Darvon-N, do not take more than **6** tablets in one day.
- If you take Darvon, do not take more than **6** capsules in one day.
- Before taking Darvon-N or Darvon, tell your doctor about all the medicines you take. Darvon-N or Darvon and many other medicines may interact with each other and may cause serious side effects. Certain medicines can affect how your liver breaks down other medicines. See “What should I tell my doctor before taking Darvon-N or Darvon?”

- Do not drink grapefruit juice or eat grapefruit while you take Darvon-N or Darvon. Grapefruit juice may interact with Darvon-N or Darvon.
- Do not drink alcohol while using Darvon-N or Darvon. Using alcohol with Darvon-N or Darvon may increase your risk of having dangerous side effects.

What are Darvon-N and Darvon?

- Darvon-N and Darvon are prescription medicines used to treat mild to moderate pain.

- Darvon-N and Darvon are federally controlled substances (C-IV) because they are strong opioid pain medicines that can be abused by people who abuse prescription medicines or street drugs.
- Prevent theft, misuse or abuse. Keep Darvon-N or Darvon in a safe place to protect it from being stolen. Darvon-N and Darvon can be a target for people who misuse or abuse prescription medicines or street drugs.
- Never give Darvon-N or Darvon to anyone else, even if they have the same symptoms that you have. It may harm them or even cause death. Selling or giving away this medicine is against the law.

It is not known if Darvon-N and Darvon are safe and effective in children younger than age 18.

Who should not take Darvon-N or Darvon?

Do not take Darvon-N or Darvon if you:

- are allergic to propoxyphene. Ask your doctor if you are not sure. See the end of this Medication Guide for a list of the ingredients in Darvon-N and Darvon.
- are having an asthma attack or have severe asthma, trouble breathing, or have a lung problem
- have a bowel blockage called paralytic ileus

What should I tell my doctor before taking Darvon-N or Darvon?

Before you take Darvon-N or Darvon, tell your doctor:

- if you have any of the conditions listed in the section "What is the most important information I should know about Darvon-N and Darvon?"
- if you are allergic to propoxyphene
- if you plan to have surgery with general anesthesia
- if you are pregnant or plan to become pregnant.
- if you take Darvon-N or Darvon regularly before your baby is born, your newborn baby may have withdrawal symptoms because their body has become used to the medicine. Symptoms of withdrawal in a newborn baby may include:
 - irritability
 - crying more than usual

- shaking (tremors)
- jitteriness
- breathing faster than normal
- diarrhea or more stools than normal
- vomiting
- fever
- if you take Darvon-N or Darvon right before your baby is born, your baby could have breathing problems.
- if you are breast-feeding or plan to breast-feed. Some Darvon-N or Darvon passes into breast milk.

Tell your doctor about all the medicines you take, including prescription, and non-prescription medicines, vitamins, and herbal supplements. Darvon-N and Darvon interacts with many medicines and may lead to serious side effects. The doses of certain medicines may need to be changed.

Especially tell your doctor if you take:

See “What is the most important information I should know about Darvon-N and Darvon?”

- certain medicines that can affect how your liver breaks down other medicines
- a monoamine oxidase inhibitor (MAOI) medicine
- other medicines that make you sleepy, such as: other medicines for pain, including other opioid medicines, anti-depressant medicines, sleeping pills, anti-anxiety medicines, muscle relaxants, anti-nausea medicines, or tranquilizers
- a blood pressure medicine
- a blood-thinner medicine. You may have an increased risk of bleeding while also taking Darvon-N or Darvon.

Ask your doctor or pharmacist if you are not sure if your medicine is one listed above.

Know the medicines you take. Keep a list of them to show to your doctor and pharmacist when you get a new medicine.

How should I take Darvon-N or Darvon?

See “What is the most important information I should know about Darvon-N and Darvon?”

- Take Darvon-N or Darvon exactly as prescribed.
- If you take too much Darvon-N or Darvon, or take it with alcohol or other medicines, you may overdose. See “What is the most important information I should know about Darvon-N or Darvon?” You will need medical help right away if you think you have taken an overdose of Darvon-N or Darvon. A large overdose could cause you to become unconscious and die.

Signs and symptoms of an overdose of Darvon-N or Darvon include:

- you are very sleepy or do not respond to others
- confusion
- have trouble breathing or stop breathing
- changes in blood pressure and heart rate

What are the possible side effects of Darvon-N and Darvon?

Darvon-N and Darvon can cause serious side effects, including:

See “What is the most important information I should know about Darvon-N and Darvon?”

- **Serious breathing problems that can become life-threatening.** This is especially true if you already have a serious lung or breathing problem, or your body is not used to opioid pain medicines. This can happen even if you take Darvon-N or Darvon exactly as prescribed by your doctor. Call your doctor or get medical help right away if:
 - your breathing slows down
 - you have shallow breathing (little chest movement with breathing)
 - you feel faint, dizzy, confused, or
 - you have any other unusual symptoms
- **Darvon-N and Darvon can cause your blood pressure to drop.** This can make you feel dizzy and faint if you get up too fast from sitting or lying down. Low blood pressure is also more likely to happen if you take other medicines that can also lower your blood pressure. Severe low blood pressure can happen if you lose blood or take certain other medicines.
- **Sleepiness.** Darvon-N and Darvon can cause sleepiness and may affect your ability to make decisions, think clearly, or react quickly. Do not drive, operate heavy machinery, or do other dangerous activities until you know how Darvon-N or Darvon affects you.
- **Darvon-N and Darvon can cause physical dependence if you take it for more than a few weeks.** Do not stop taking Darvon-N or Darvon all of a sudden. You could become sick with uncomfortable withdrawal symptoms (for example, nausea, vomiting, diarrhea, anxiety, and shivering) because your body has become used to the medicine. Physical dependence is not the same as drug addiction. Your doctor can tell you more about the differences between physical dependence and drug addiction.

Tell your doctor if you have any of these withdrawal symptoms while you slowly stop taking Darvon-N or Darvon. You may need to stop Darvon-N or Darvon more slowly.

Common side effects of Darvon-N and Darvon include:

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| • dizziness | • weakness |
| • feeling sleepy | • feeling of excitement (elation) or discomfort |
| • nausea and vomiting | • seeing, hearing, or sensing things that are not really there (hallucinations) |
| • constipation | • blurred vision |
| • stomach area (abdominal) pain | |
| • skin rashes | |
| • lightheadedness | |
| • headache | |

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

You may also report side effects to Xanodyne Pharmaceuticals, Inc. at 1-877-773-7793.

How should I store Darvon-N and Darvon?

- Store Darvon-N between 59°F to 86°F (15°C to 30°C).
- Store Darvon between 68°F to 77°F (20°C to 25°C).

Keep Darvon-N, Darvon and all medicines out of the reach of children.

General information about Darvon-N and Darvon

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Darvon-N or Darvon for a purpose for which it was not prescribed. Do not give Darvon-N or Darvon to others even if they have the same symptoms you have. It may harm them and is against the law.

This Medication Guide summarizes the most important information about Darvon-N and Darvon. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about Darvon-N and Darvon that is written for health professionals. For more information, go to www.Xanodyne.com or call 1-877-773-7793.

What are the ingredients in Darvon-N and Darvon?

Darvon-N:

Active ingredient: propoxyphene napsylate

Inactive ingredients: cellulose, cornstarch, iron oxides, lactose, magnesium stearate, silicon dioxide, stearic acid, and titanium dioxide

Darvon:

Active ingredient: propoxyphene hydrochloride

Inactive ingredients: D & C Red No. 33, FD & C Yellow No. 6, gelatin, magnesium stearate, silicone, starch, titanium dioxide, and other inactive ingredients

Xanodyne Pharmaceuticals, Inc.
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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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