

MEDICATION GUIDE
DARVOCET-N® 50 [dar-vo-cet-N]
(C-IV)
(propoxyphene napsylate and acetaminophen)
tablets

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(C-IV)
(propoxyphene napsylate and acetaminophen)
tablets

Read this Medication Guide before you start taking Darvocet-N 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 Darvocet-N?

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

Overdoses by accident or on purpose (intentional overdose). Overdoses with Darvocet-N 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 Darvocet-N.** Many of the deaths that happen in people who take Darvocet-N 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 Darvocet-N without talking to your doctor.**

- **Before taking Darvocet-N 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 Darvocet-N exactly as prescribed. Do not change your dose or stop taking Darvocet-N without first talking to your doctor.

- If you take Darvocet-N 100, do not take more than **6** tablets in one day.
- If you take Darvocet-N 50, do not take more than **12** tablets in one day.

- Before taking Darvocet-N, tell your doctor about all the medicines you take. Darvocet-N 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 Darvocet-N?”
- Do not drink grapefruit juice or eat grapefruit while you are taking Darvocet-N. Grapefruit juice may interact with Darvocet-N.
- Do not drink alcohol while using Darvocet-N. Using alcohol with Darvocet-N may increase your risk of having dangerous side effects.

What is Darvocet-N?

- Darvocet-N is a prescription medicine that contains two medicines: propoxyphene and acetaminophen. Darvocet-N is used to relieve mild to moderate pain.

- Darvocet-N is a federally controlled substance (C-IV) because it is a strong opioid pain medicine that can be abused by people who abuse prescription medicines or street drugs.
- Prevent theft, misuse or abuse. Keep Darvocet-N in a safe place to protect it from being stolen. Darvocet-N can be a target for people who misuse or abuse prescription medicines or street drugs.
- Never give Darvocet-N 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 Darvocet-N is safe and effective in children under age 18.

Who should not take Darvocet-N?

Do not take Darvocet-N if you:

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

What should I tell my doctor before taking Darvocet-N?

Before taking Darvocet-N, tell your doctor:

- if you have any of the conditions listed in the section “What is the most important information I should know about Darvocet-N?”
- if you are allergic to propoxyphene or acetaminophen
- if you plan to have surgery with general anesthesia
- if you are pregnant or plan to become pregnant.

- if you take Darvocet-N 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 Darvocet-N right before your baby is born, your baby could have breathing problems.
- if you are breast-feeding or plan to breast-feed. Some Darvocet-N passes into breast milk.

Tell your doctor about all the medicines you take, including prescription, and non-prescription medicines, vitamins, and herbal supplements. Darvocet-N 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 Darvocet-N?”

- 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
- an anticholinergic medicine
- a water pill (diuretic)
- a medicine for high blood pressure or irregular heart beat
- birth control pills taken by mouth
- lamotrigine (Lamictal, Lamictal CD, Lamictal XR, Lamictal ODT)
- probenecid (Probalan)
- a blood-thinner medicine. You may have an increased risk of bleeding while also taking Darvocet-N.
- zidovudine (Trizivir, Combivir, Retrovir)

Do not take other medicines that contain acetaminophen while taking Darvocet-N. See “What are the possible side effects of Darvocet-N?”

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 Darvocet-N?

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

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

Signs and symptoms of an overdose of Darvocet-N 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
- nausea
- vomiting
- loss of appetite
- stomach area (abdominal pain)

What are the possible side effects of Darvocet-N?

Darvocet-N can cause serious side effects, including:

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

- **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 Darvocet-N 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
- **Darvocet-N 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.
- **Liver problems.** Darvocet-N contains acetaminophen. Acetaminophen can cause serious liver problems if you take more than the recommended dose. Do not take more Darvocet-N than prescribed. See “How should I take Darvocet-N?” **Do not take any other medicines that contain acetaminophen while also taking Darvocet-N. Many products contain acetaminophen. Ask your doctor or pharmacist if you are not sure.** Liver damage may happen even after symptoms go away. You can die from liver failure days later. Tell your doctor if you have any of these symptoms of a liver problem while taking Darvocet-N:
 - nausea
 - vomiting
 - loss of appetite
 - stomach area (abdominal pain)

- **Sleepiness.** Darvocet-N 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 Darvocet-N affects you.
- **Darvocet-N can cause physical dependence if you take it for more than a few weeks.** Do not stop taking Darvocet-N 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. Talk to your doctor about slowly stopping Darvocet-N to avoid getting sick with withdrawal symptoms. 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 Darvocet-N. You may need to stop Darvocet-N more slowly.

Common side effects of Darvocet-N 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 Darvocet-N?

- Store Darvocet-N at 59°F to 86°F (15°C-30°C).

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

General information about Darvocet-N

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Darvocet-N for a purpose for which it was not prescribed. Do not give Darvocet-N 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 Darvocet-N. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about Darvocet-N 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 Darvocet-N?

Active ingredients: propoxyphene napsylate and acetaminophen

Inactive ingredients: amberlite, cellulose, FD&C Yellow No.6, magnesium stearate, stearic acid, titanium dioxide, and other inactive ingredients.

Xanodyne Pharmaceuticals, Inc.
Newport, KY 41071

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

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