Propoxyphene / Darvon® Compound-65 Pulvules® / Darvon® Pulvules® /

Darvon-N® / E-Lor® / PC-CAP® / Wygesic® / Darvocet A500® /

Darvocet-N® 100 / Darvocet-N® 50 / Propocet® 100

Why is this medication prescribed?

Propoxyphene (and other brand names listed above) are used to relieve mild to moderate pain. This medication is sometimes prescribed for other uses; ask your doctor or pharmacist for more information.

How should this medicine be used?

Propoxyphene comes as a tablet, capsule, and liquid to take by mouth. It usually is taken every 4 hours as needed. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take propoxyphene exactly as directed. Propoxyphene can be habit-forming.

Shake the liquid well before each use.

What special precautions should I follow?

Before taking propoxyphene,

- tell your doctor and pharmacist if you are allergic to propoxyphene or any other drugs.
- tell your doctor and pharmacist what prescription and nonprescription medications you are taking, especially other pain relievers; anticoagulants ('blood-thinners') such as warfarin (Coumadin); antidepressants; antihistamines; medications for cough, cold, or allergies; muscle relaxants; sedatives; seizure medications; sleeping pills; tranquilizers; and vitamins.
- tell your doctor if you have or have ever had liver or kidney disease, or a history of alcoholism.
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking propoxyphene, call your doctor.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking propoxyphene.
- you should know that this drug may make you drowsy. Do not drive a car or operate machinery until you know how this drug affects you.
- remember that alcohol can add to the drowsiness caused by this drug.

What should I do if I forget a dose?

Propoxyphene usually is taken as needed. If your doctor has told you to take propoxyphene regularly, take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Propoxyphene may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- dizziness
- lightheadedness
- drowsiness
- upset stomach
- vomiting
- constipation
- stomach pain
- skin rash
- mood changes
- headache

If you experience the following symptom, call your doctor immediately:

- difficulty breathing

What storage conditions are needed for this medicine?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom). Throw away any medication that is outdated or no longer needed. Talk to your pharmacist about the proper disposal of your medication.

In case of emergency/overdose

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

What other information should I know?

Keep all appointments with your doctor. Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

IMPORTANT WARNING:

Propoxyphene in high doses, taken by itself or in combination with other drugs, has been associated with drug-related deaths. Do not take propoxyphene in combination with other drugs that cause drowsiness:

alcohol, tranquilizers, sleep aids, antidepressant drugs, or antihistamines. Do not take a larger dose, take it more often, or for a longer period than your doctor tells you to.

[Posted 7/7/2009] FDA notified healthcare professionals that it is taking several actions to reduce the risk of overdose in patients using pain medications that contain propoxyphene because of data linking propoxyphene and fatal overdoses. The agency will require manufacturers of propoxyphene-containing products to strengthen the label, including the boxed warning, emphasizing the potential for overdose when using these products and to provide a medication guide to patients stressing the importance of using the drugs as directed.

FDA is requiring a new safety study assessing unanswered questions about the effects of propoxyphene on the heart at higher than recommended doses. Findings from this study, as well as other data, could lead to additional regulatory action. To further evaluate the safety of propoxyphene, FDA plans to work with several groups including the Centers for Medicare & Medicaid Services and the Veterans Health Administration to study how often the elderly are prescribed propoxyphene instead of other pain relievers and the difference in the safety profiles of propoxyphene compared to other drugs. For more information visit the FDA website at: http://www.fda.gov/Safety/MedWatch/SafetyInformation and http://www.fda.gov/Drugs/DrugSafety.

If you have any questions or concerns about this medication

please feel free to call the office at 602.653.0540

or e-mail at info@getyourbodyrochlin.com.

Have a beautiful day!

www.getyourbodyrochlin.com

I, (*sign here*) _____, have received and been instructed to review these 3 pages of information regarding:

Propoxphene / Darvon / Darvocet