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AVAILABILITY: Discontinued.

Darvocet

Generic Name: acetaminophen and propoxyphene (a SEET a MIN oh fen and proe POX i feen) **Brand Names:** *Balacet, Darvocet, Propacet 100*

What is Darvocet?

Darvocet (acetaminophen and propoxyphene) was withdrawn from the U.S. market in November 2010.

Darvocet contains a combination of **propoxyphene** and **acetaminophen**. Propoxyphene is in a group of drugs called narcotic pain relievers. Acetaminophen is a less potent pain reliever and a fever reducer that increases the effects of propoxyphene.

Darvocet is used to relieve mild to moderate pain with or without fever.

Darvocet may also be used for purposes not listed in this medication guide.

Important information

Darvocet was withdrawn from the U.S. market in November 2010.

Propoxyphene may be habit-forming and should be used only by the person it was prescribed for. Keep the medication in a secure place where others cannot get to it. Do not use Darvocet if you have taken an MAO inhibitor such as furazolidone (Furoxone), isocarboxazid (Marplan), phenelzine (Nardil), rasagiline (Azilect), selegiline (Eldepryl, Emsam), or tranylcypromine (Parnate) in the last 14 days. Serious, life threatening side effects can occur if you use Darvocet before the MAO inhibitor has cleared from your body.

Before taking this medicine

Do not use Darvocet if you are allergic to acetaminophen (Tylenol) or propoxyphene. Propoxyphene may be habit-forming and should be used only by the person it was prescribed for. Never share Darvocet with another person, especially someone with a history of drug abuse or addiction. Keep the medication in a place where others cannot get to it. Do not use Darvocet if you have used an MAO inhibitor such as furazolidone (Furoxone), isocarboxazid (Marplan), phenelzine (Nardil), rasagiline (Azilect), selegiline (Eldepryl, Emsam, Zelapar), or tranylcypromine (Parnate) in the last 14 days. A dangerous drug interaction could occur, leading to serious side effects.

To make sure you can safely take Darvocet, tell your doctor if you have any of these other conditions:

- asthma, COPD, sleep apnea, or other breathing disorders;
- liver or kidney disease;
- a history of head injury or brain tumor;
- a gallbladder or pancreas disorder;
- a stomach or intestinal disorder;

- suicidal thoughts or behavior; or
- mental illness, or a history of drug or alcohol addiction.

Tell your doctor if you drink more than three alcoholic beverages per day or if you have ever had alcoholic liver disease (cirrhosis). You may not be able to take medication that contains acetaminophen.

FDA pregnancy category C. It is not known whether Darvocet is harmful to an unborn baby, but it could cause breathing problems or addiction/withdrawal symptoms in a newborn. Tell your doctor if you are pregnant or plan to become pregnant during treatment. Acetaminophen and propoxyphene can pass into breast milk and may harm a nursing baby. Do not use Darvocet without telling your doctor if you are breast-feeding a baby.

How should I take Darvocet?

Take Darvocet exactly as prescribed by your doctor. Do not take in larger or smaller amounts or for longer than recommended. Follow the directions on your prescription label. Tell your doctor if the medicine seems to stop working as well in relieving your pain.

An overdose of acetaminophen can damage your liver. Adults should not take more than 1 gram (1000 mg) of acetaminophen per dose or 4 grams (4000 mg) per day. If you drink more than three alcoholic beverages per day, you should never use more than 2 grams (2000 mg) of acetaminophen per day. Do not stop using Darvocet suddenly, or you could have unpleasant withdrawal symptoms. Ask your doctor how to avoid withdrawal symptoms when you stop using Darvocet. If you need surgery, tell the surgeon ahead of time that you are using acetaminophen and proposyphene. You may need to stop using the medicine for a short time.

Store Darvocet at room temperature away from moisture and heat. Keep track of the amount of medicine used from each new bottle. Propoxyphene is a drug of abuse and you should be aware if anyone is using your medicine improperly or without a prescription.

What happens if I miss a dose?

Since Darvocet is taken as needed, you may not be on a dosing schedule. If you are taking the medication regularly, take the missed dose as soon as you remember. Skip the missed dose if it is almost time for your next scheduled dose. Do not take extra medicine to make up the missed dose.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222. An overdose of Darvocet can be fatal.

Overdose symptoms may include extreme drowsiness, nausea, vomiting, dark urine, jaundice (yellowing of the skin or eyes), pinpoint or dilated pupils, confusion, seizure (convulsions), cold and clammy skin, blue lips, weak pulse, slow or uneven heart rate, shallow breathing, fainting, or breathing that stops.

What should I avoid?

Darvocet may impair your thinking or reactions. Be careful if you drive or do anything that requires you to be alert. Ask a doctor or pharmacist before using any other cold, allergy, pain, or sleep medication. Acetaminophen (sometimes abbreviated as "APAP") is contained in many combination medicines. Taking certain products together can cause you to get too much acetaminophen. Check the label to see if a medicine contains acetaminophen or APAP. Drinking alcohol can increase certain side effects of Darvocet.

Darvocet side effects

Get emergency medical help if you have any of these signs of an allergic reaction to Darvocet: hives; difficulty breathing; swelling of your face, lips, tongue, or throat. Call your doctor at once if you have a serious side effect such as:

- shallow breathing, slow heartbeat, feeling like you might pass out;
- chest pain, feeling short of breath;
- confusion, unusual thoughts or behavior;
- seizure (convulsions); or
- nausea, stomach pain, loss of appetite, itching, dark urine, clay-colored stools, jaundice (yellowing of the skin or eyes).

Less serious Darvocet side effects include:

- feeling dizzy or drowsy;
- mild nausea, vomiting, upset stomach, constipation;
- headache, blurred vision; or
- dry mouth.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What other drugs will affect Darvocet?

Cold or allergy medicine, sleeping pills, muscle relaxers, antidepressants, or seizure medication can add to sleepiness caused by propoxyphene, or could slow your breathing. Tell your doctor if you regularly use any of these medicines, or any other narcotic medications.

Tell your doctor about all other medications you use, especially:

- aspirin or a blood thinner such as warfarin (Coumadin);
- birth control pills;
- dexamethasone (Decadron, Hexadrol);
- a diuretic (water pill) such as furosemide (Lasix);
- St. John's wort;
- an antibiotic such as clarithromycin (Biaxin), erythromycin (E.E.S., EryPed, Ery-Tab, Erythrocin), rifabutin (Mycobutin), rifampin (Rifadin, Rifater, Rifamate), or rifapentine (Priftin);
- an antidepressant such as nefazodone;
- antifungal medication such as fluconazole (Diflucan), itraconazole (Sporanox), ketoconazole (Nizoral), or voriconazole (Vfend);
- a barbiturate such as phenobarbital (Solfoton);
- heart or blood pressure medication such as amiodarone (Cordarone, Pacerone), diltiazem (Cartia, Cardizem), nifedipine (Nifedical, Procardia), propranolol (Inderal), verapamil (Calan, Covera, Isoptin, Verelan), and others;
- HIV or AIDS medicine such as fosamprenavir (Lexiva), nelfinavir (Viracept), ritonavir (Norvir), zidovudine (Retrovir), and others; or

• seizure medication such as carbamazepine (Carbatrol, Tegretol), lamotrigine (Lamictal), phenytoin (Dilantin), and others.

This list is not complete and there are many other drugs that can interact with Darvocet. Tell your doctor about all the prescription and over-the-counter medications you use. This includes vitamins, minerals, herbal products, and drugs prescribed by other doctors. Do not start using a new medication without telling your doctor.

Where can I get more information?

- Your pharmacist can provide more information about Darvocet.
- Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use Darvocet only for the indication prescribed.
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