



RJ Health Systems
Make Sense of Drug Intelligence

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FLASH!

Pharmacy Bulletin

VOLUME 2, ISSUE 10

SEPTEMBER 15TH, 2009

FDA Allows Propoxyphene to Stay on the Market

The U.S. Food and Drug Administration (FDA) is taking action on its concerns with the opioid medication, Propoxyphene, for its increased risk of fatal overdose when using medicines that contain propoxyphene, such as Darvon and Darvocet. The FDA is requiring that manufacturers of propoxyphene-containing products strengthen the label's boxed warning to address the risk of overdose with these products. They are also required to develop a Medication Guide, which is FDA-approved labeling that must be given to patients with each new prescription or refill.

The FDA also says that physicians should be aware of the risk for overdose when prescribing these drugs. They are advised to carefully review the history of their patients and make appropriate treatment decisions based on warnings and directions stated within the drug's label.

Based on evidence, the FDA has concluded that the benefits that propoxyphene provides outweigh the safety risks and will therefore continue to stay on the market while they continue to investigate the safety of the drug, along with other Federal agencies (e.g., Centers for Medicare and Medicaid Services and the Department of Veterans Affairs).

There are many unanswered questions regarding the safety of propoxyphene and the risk of overdose. Accordingly, the FDA is requiring manufacturers of propoxyphene-containing drugs to conduct safety studies of the effects of propoxyphene on the heart at higher than recommended doses.

Darvocet-N® 50 and Darvocet-N® 100 Label:

WARNINGS

- **There have been numerous cases of accidental and intentional overdose with propoxyphene products either alone or in combinations with other CNS depressants, including alcohol. Fatalities within the first hour of overdosage are not uncommon. Many of the propoxyphene-related deaths have occurred in patients with previous histories of emotional disturbances or suicidal ideation/ attempts and/or concomitant administration of sedatives, tranquilizers, muscle relaxants, antidepressants, or other CNS-depressant drugs. Do not prescribe propoxyphene for patients who are suicidal or have a history of suicidal ideation.**
- **The metabolism of propoxyphene may be altered by strong CYP3A4 inhibitors (such as ritonavir, ketoconazole, itraconazole, troleandomycin, Clarithromycin, nelfinavir, nefazadone, amiodarone, amprenavir, aprepitant, diltiazem, erythromycin, Fluconazole, fosamprenavir, grapefruit juice, and verapamil) leading to enhanced propoxyphene plasma levels. Patients receiving propoxyphene and any CYP3A4 inhibitor should be carefully monitored for an extended period of time and dosage adjustments should be made if warranted (see CLINICAL PHARMACOLOGY—Drug Interactions, WARNINGS, PRECAUTIONS and DOSAGE AND ADMINISTRATION for further information).**

For more information, visit <http://www.fda.gov>



DRUG RECALL: Teva Pharmaceuticals Inc. and Apotex Inc. Products

The following products have been recalled:

Teva Pharmaceuticals Inc. -

Product name and Strength:	NDC #:	LOT #'s (EXPIR.):
Clonazepam Tablets 0.5 mg (100's)	0093-0832-01	35200199A (02/10), 35200200A (02/10) 35200436A (09/10), 35200437A (09/10) 35200460A (09/10), 35200462A
Clonazepam Tablets 1.0mg (100's)	0093-0833-01	35200199A (02/10), 35200200A (02/10) 35200201A (02/10), 35200218A (02/10) 35200219A (02/10), 35200278A (02/10)

*This recall is being carried out because some tablets may exceed weight requirements.

Apotex Inc. -

Product name and Strength (Size):	NDC #:	LOT #'s:
Gemfibrozil Tabs 600mg (500)	60505-0034-8	HK9383, JC8521, JC8522
Omeprazole Caps 20mg (1000)	60505-0065-1	HZ2537
Clonazepam Tabs 1mg (100)	60505-0067-1	HY6843
Clonazepam Tabs 1mg (500)	60505-0067-3	HW7772
Paroxetine Tabs 10mg (30)	60505-0097-1	HY6618
Paroxetine Tabs 10mg (1000)	60505-0097-4	HY6617
Paroxetine Tabs 40mg (30)	60505-0101-1	JE1712
Paroxetine Tabs 40mg (1000)	60505-0101-4	JE5041, JE5042
Etodolac Tabs 500mg (100)	60505-0102-1	HN6979, JA2056
Cyclosporine Caps 25mg (30)	60505-0133-0	JE8043
Cyclosporine Caps 100mg (30)	60505-0134-0	HP9575
Diclofenac Pot Tab 50mg (100)	60505-0135-0	HX3580
Omeprazole Caps 40mg (30)	60505-0146-0	JE1347
Quinapril Tabs 10mg (1000)	60505-0173-1	HL2342, HY4714
Quinapril Tabs 20mg (1000)	60505-0174-1	HR5819, HY4721, HZ9653, JD7365
Quinapril Tabs 40mg (1000)	60505-0175-1	HX6618, HY4735 HZ9652, JD7367
Amlodipine Besylate Tabs 10mg (1000)	60505-0195-3	HP3312, HR2621, HV1015
Torsemide Tabs 20mg (100)	60505-0234-1	HT4487
Benazepril Tabs 20mg (100)	60505-0267-1	JA5536
Benazepril Tabs 40mg (100)	60505-0268-1	JA5540, JC2294
Lithium Carb Caps 300mg (100)	60505-2504-1	HT3527, HT3529, HT3533
Carvedilol Tabs 3.125mg (100)	60505-2606-1	HN1349
Carvedilol Tabs 6.25mg (100)	60505-2607-1	HP0602

*Apotex is conducting a recall of the items listed above in order to meet FDA audit criteria.

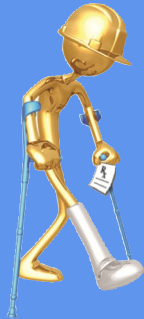
For more information please visit: <http://www.tevapharm.com/> and <http://www.apotex.com/global/default.asp>



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Chronic Low Back Pain Reduced With Use of Cymbalta®

In a recent study involving 181 patients with chronic low back pain during an open-label 41-week trial, researchers studied and evaluated the long-term pain relief maintenance effect in patients while taking duloxetine, the active ingredient in Cymbalta®, 60mg or 120mg once daily. There was a preliminary study that the patients completed, consisting of a 13-week placebo-controlled acute phase. The study showed that approximately 32% of the patients experienced at least 30% pain reduction from baseline during the 13-week, placebo-controlled acute phase of the study.

Most common side effects from the study included headache, nausea, upper abdominal pain, excessive sweating (hyperhidrosis), back pain, diarrhea and fatigue. A total of 18 patients discontinued due to adverse events during the extension phase. Patients completing the acute phase on duloxetine remained on the same dose for the remaining 28 weeks while those on placebo were switched to duloxetine. Maintenance of effect was assessed in 58 duloxetine patients who were responders at the end of the acute phase.

Chronic low back pain affects approximately 4 to 33 percent of the world's population at any one time. Chronic pain is defined as pain that persists beyond acute pain or beyond the expected time for an injury to heal. Men and women are equally affected by chronic low back pain, and it occurs most often between the ages of 30 and 50.

For more information, please visit:
<http://www.medicalnewstoday.com/articles/163758.php>

FDA Update Regarding Stolen Insulin

The Food and Drug Administration (FDA) has updated the public on the 129,000 stolen vials (three different lots) of Levemir® insulin made by Novo Nordisk Inc.. They have gathered evidence showing that the stolen vials were not handled or stored correctly, resulting in dangerous side effects if used. The agency has received multiple reports of patients who suffered an adverse event due to poor control of glucose levels after using a vial from one of the stolen lots.

So far only about two (2) percent of the 129,000 vials has been recovered. The FDA continues to investigate this matter and is asking the public for assistance in reporting any information regarding these vials to the FDA's Office of Criminal Investigations (OCI) by calling 800-551-3989 or by visiting <http://www.fda.gov/ICECI/CriminalInvestigations/default.htm>

Patients taking Levemir® are reminded to check for the following lots: XZF0036; XZF0037; XZF0038. If they have one of these lots, they are instructed to discontinue use and replace it with a vial from another lot. If you wish to switch to another brand, first contact your health care provider because another insulin product may require adjustments to dosing.

RECALL: Caraco Pharmaceutical's Methimazole Tablets

Caraco Pharmaceutical has recalled the below products because they have determined that the lots may not meet specification throughout the labeled expiry period.

Product: Methimazole Tabs 5mg (100's)
NDC #: 57664-458-88
Lot #'s: 80008A, 81584A, 90331A, 90313A, 90658A

Product: Methimazole Tabs 10mg (100's)
NDC#: 57664-459-88
Lots #'s: 80012A, 80013A, 81718B, 82566A, 82567A

For more information visit: <http://www.caraco.com/>