



**URGENT NOTICE**

## **TYPE: RECALL**

*Hypertension Pill Found in Nausea Drug Bottles*

Drug Name: **Promethazine HCl Tablets 25mg**

Audience: PHARMACY

Date: **05/30/2014**

### **ISSUE**

Zydus Pharmaceuticals announced a voluntary recall of 10,200 bottles of Promethazine HCl Tablets 25mg. This recall was initiated due to the reported presence of an Atenolol 25mg tablet in a Promethazine HCl 25mg tablet bottle. Atenolol is indicated for the long-term management of angina in adults and hypertension. In accordance with published guidance regarding aseptic processing simulation from the FDA, NPC has initiated this recall as a precautionary measure.

The affected 25mg tablets are supplied in 100-count bottles have Lot #MN9081 with an expiration date of 09/15 and starting with an NDC of '68382'. The recalled lot was manufactured at a Zydus Pharmaceuticals plant in India. The FDA has designated this a Class II recall, in which use of or exposure to this product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

### **BACKGROUND**

Promethazine HCl is indicated for the treatment of motion sickness and perioperative nausea and vomiting in children and adults.

### **RECOMMENDATION**

If you have any patients taking this drug, please contact them immediately. NPC is also asking retailers to remove the affected lots from store shelves and is asking consumers to discontinue use and dispose of any product they may have that is included in this recall.

*For more information call (888) 463-6332 or visit [FDA.gov](http://FDA.gov).*

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