Information for Healthcare Professionals

Promethazine Hydrochloride
(marketed as Phenergan and generic products)

FDA ALERT [04/2006]: Medications containing promethazine hydrochloride (HCl) should not be used for children less than two years of age because of the potential for fatal respiratory depression. This includes promethazine HCl in any form: syrups, suppositories, tablets, or injectables. Cases of respiratory depression including fatalities have been reported with use of promethazine HCl in children less than two years of age. Caution should also be exercised when administering promethazine HCl in any form to pediatric patients two years of age and older. The labeling on all products, brand name and generic, has been changed to reflect these strengthened warnings. One manufacturer of suppositories and tablets has notified healthcare professionals of the changed label. The FDA is issuing this safety alert to make sure that healthcare professionals, other caregivers, and patients realize that the warnings apply to promethazine HCl syrups as well.

This information reflects FDA's current analysis of data available to FDA concerning this drug. FDA intends to update this sheet when additional information or analyses become available.

To report any unexpected adverse or serious events associated with the use of this drug, please contact the FDA MedWatch program using the contact information at the bottom of this sheet.

Considerations

Healthcare professionals, other caregivers, and patients should consider the following:

- All medications containing promethazine HCl—syrups, suppositories, injectables, and tablets— are contraindicated for use in pediatric patients less than two years of age because of the potential for fatal respiratory depression.
- Caution should also be exercised when administering promethazine HCl medications to pediatric patients two years of age and older.

Wyeth, a company which markets tablets and suppositories under the brand name Phenergan, has changed the product labeling to show that the drug is contraindicated in children under two. Wyeth sent a letter to healthcare professionals, alerting them of the labeling change for their tablet and suppository products. Wyeth is not marketing syrups, but some generic companies still do. The generic labels also have been changed.

Data Summary

Promethazine HCl, an antihistamine, is marketed as tablets, suppositories, injectables, and syrups. The drug is not for children under two, because it can cause serious side effects, including respiratory depression that could be fatal. FDA has received reports of serious adverse events, including seven deaths in children under two. The FDA sent a letter to the editor of the New England Journal of Medicine (NEJM) explaining the context for the seven deaths, based on a 2004 review of the Adverse Event Reporting System: Starke P. R., Weaver J., Chowdhury B. A., *N Engl J Med* 2005; **352**:2653 (http://content.nejm.org/cgi/content/full/352/25/2653?ijkey=xNrx2F2RcFfHc&keytype=ref&siteid=nejm).