

Mercury Poisoning in Child Treated with Aqueous Merthiolate®

[Thimerosal Topical Solution, U.S.P. (1:1000)]

The Ohio Board of Pharmacy has received an investigative report from the Ohio Department of Health's Division of Epidemiology regarding the death of a 21-month old child due to mercury poisoning. The investigation strongly implicated the Thimerosal solution as "the source of mercury that subsequently resulted in the child's death" since no other source could be identified. The poisoning apparently resulted from the improper use of Thimerosal Topical Solution, U.S.P. (1:1000), prescribed by a physician for the treatment of chronic otitis media.

The investigation disclosed that the child had a history of recurrent otitis media and in July 1981 had polyethylene ventilation tubes placed in both ears. In February 1982 the child was diagnosed as having otitis media in the left ear and was placed on antibiotics. A few days later, a prescription was issued for one pint of Merthiolate® solution (1:1000) with one refill. The prescription sig. indicated the ear was to be irrigated with one ounce of the solution on a daily basis.

The irrigations continued for approximately eight days and were then increased to twice-a-day for approximately four weeks. During this time period, two pints of the Thimerosal solution were obtained by prescription and one pint purchased over-the-counter. Approximately two and one-half pints were used over a five-week period to irrigate the left ear of the child.

According to the investigative report, the parents were instructed to irrigate the ear by placing the syringe into the polyethylene ventilation tube and pumping the Merthiolate® solution through the tympanic membrane into the inner ear. This method resulted in the child ingesting the approximately two and one-half pints of the mercury-containing product over the five-week period.

While the use of Thimerosal solution (1:1000) for the treatment of otitis media appears to be a common practice only in the Central Ohio area, the Board of Pharmacy is issuing this Advisory regarding the use and sale of Thimerosal Topical Solution (1:1000). Thimerosal Topical Solution, U.S.P. (1:1000) is a stable, saline, borate-buffered solution of an organic-mercury compound, is indicated for use as a topical antiseptic,

and is available as an over-the-counter drug product.

In January 1982 the federal Food and Drug Administration *proposed* a rule classifying Thimerosal, and all other over-the-counter mercury-containing drug products for topical antimicrobial use, as not generally recognized as safe and effective and as being misbranded [47 FR 436]. As of April 20, 1983, the rule has not been adopted.

The proposed rule by F.D.A. was based on the "Advisory Review Panel on OTC Miscellaneous External Drug Products" recommendations concerning OTC mercury-containing drug products. The Panel concluded that "Thimerosal is not safe for OTC topical use because of its potential for cell damage if applied to broken skin and its allergy potential. It is not effective as a topical antimicrobial because its bacteriostatic action can be reversed."

Studies conducted by physicians at Children's Hospital in Columbus, Ohio, however, indicate that Thimerosal solution (1:1000) is effective in the treatment of otitis media and is safe if used correctly. Correct use involves "flushing" the ear with the solution with the head tilted and, after a few seconds, tilt the head in the opposite direction to let the ear drain." It is also recommended that treatment with Thimerosal solution should not continue beyond a period of two weeks.

The Thimerosal solution should *not* be forcibly introduced through drainage tubes into the middle ear. Precautions should be taken when using Thimerosal solution (1:1000). Whenever there is a potential for ingestion or absorption from broken or abraded skin or mucous membranes. Pharmacists should alert patients regarding the proper use of the product and point out the cautions appearing on the label, especially where the product has been prescribed or is being purchased for use on an infant. Accordingly, the product should not be available for purchase without the advice of a pharmacist and cautions concerning its proper use. □

**Minutes of the Annual Meeting
and Committee Reports
will be in the August Journal**