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FDA Warning for Aluminum-containing Antiperspirants

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Background

Effective December 9, 2004 the FDA required that the following warning appear on all over-the-counter aluminum-containing antiperspirant drug products: "Ask a doctor before use if you have kidney disease."¹ The antiperspirant active ingredients are salts or complexes of aluminum with chloride, chlorohydrate, chlorohydrate-glycol, dichlorohydrate, sesquichlorohydrate, sulfate, or zirconium.²

Commentary

The FDA's concern is that people with renal dysfunction may not be aware that daily use of aluminum-containing antiperspirant products may put them at higher risk of kidney problems.¹ Transdermal absorption of aluminum can occur.^{3,4} Those with normal renal function do not accumulate aluminum but excrete the small quantities absorbed via the urine. Patients with diminished renal function tend to accumulate aluminum. Elevated levels of aluminum may cause neurotoxicity, possibly by inhibition of neuronal microtubule formation and competition with cations. Long-term effects can cause microcytic anemia, abnormal muscle tremor such as involuntary jerking movements, dementia, slurred speech, seizures, and osteomalacia.⁵

Some nephrologists believe that this recommendation by the FDA is based on false assumptions that toxic amounts of aluminum may be absorbed through the skin. Rather, the problem of aluminum accumulation in patients with kidney disease results from either oral aluminum-containing antacids used as phosphate binders or from aluminum-contaminated sterile water used to prepare dialysate fluid.⁶

The FDA requires aluminum-containing antacid products to be labeled with warnings of aluminum accumulation in patients with kidney disease. Elevated plasma-aluminum levels result from prolonged use in patients with renal failure

and can result in worsening of dialysis osteomalacia and encephalopathy. Aluminum is not well removed by dialysis because of its protein binding.⁷

Aluminum accumulation has been portrayed as a possible cause of Alzheimer's and other diseases. In the FDA's review of numerous studies, they conclude that aluminum can be associated with recognizable specific neurologic effects with high-doses and long-term exposure. But the FDA considers the evidence insufficient to link aluminum to Alzheimer's disease as well as Parkinson's or amyotrophic lateral sclerosis.²

Candy et al reported the accumulation of aluminum in renal failure patients with long-term exposure to aluminum-containing phosphate binder antacids. Post mortem brain examinations showed correlations between brain-aluminum concentration and aluminum exposure levels. Yet, these patients did not have dialysis encephalopathy.⁸

In a case-controlled study of 130 patient-matched pairs the association between aluminum exposure and Alzheimer's from lifetime use of antiperspirants and antacids was examined. Results from this study were inconclusive.⁹ In a review by Rowan it was concluded that the association between aluminum and Alzheimer's is a controversial issue.¹⁰

Despite the controversy of aluminum accumulation from long-term antiperspirant use and the potential for increased risk, it is a good reminder for people with hypertension or diabetes to have their kidney function checked. Too often people are unaware of kidney problems. Elevated blood pressure or diabetes may be initial signs of problems.

Patients with suspected or diagnosed kidney problems should be encouraged to take non-aluminum-containing antacids and to use deodorants. Deodorants do not contain aluminum.

More . . .

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