

The antiperspirant label warning statement is: “Ask a doctor before use if you have kidney disease”

1. As of December 2004, the FDA requires that all antiperspirant products containing aluminum include a warning that advises people with kidney disease to consult a physician before using the product.
2. FDA considers antiperspirants safe and effective; otherwise, they would not allow them to be marketed. The FDA’s concern is limited only to those consumers with kidney disease. For those consumers, the FDA believes the warning is a necessary condition for safe use of the product.
 - Aluminum is one of the most abundant elements in the environment and exposure to it occurs normally everyday - via the food we eat, the water we drink and the air we breathe.
 - Aluminum has been used safely in antiperspirant products for more than 100 years.
3. The new antiperspirant warning label is targeted at a specific segment of kidney disease patients.
 - “Kidney disease” is a non-specific term that is used to describe a broad range of kidney dysfunction.
 - In general, the new warning statement is meant for patients with kidney disease who may not be able to excrete the low levels of aluminum in the body that may result from antiperspirant use. This would be individuals with advanced chronic kidney disease (corresponding clinically to stage 4 or stage 5 chronic kidney disease¹). Such individuals have approximately 30% or less of their original normal kidney function.
 - If you have any questions about whether you have such a chronic reduction in your kidney function, you should discuss it with your doctor.

Questions & Answers

1. **Why is the warning on antiperspirant products?**

The FDA requires all antiperspirant products to include a warning statement that advises people with kidney disease to consult a physician before using the product. Since the kidneys play an important role in eliminating aluminum from the body, the FDA decided it was prudent to alert consumers who have kidney disease to the fact that their exposure to aluminum from use of antiperspirants might need to be discussed with their doctor. However, the FDA did not specify what they meant by “kidney disease.”

¹ Levey, A.S. et al. (2003) National Kidney Foundation Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification, and Stratification. *Annals of Internal Medicine*, Vol. 139(2), p. 137-147.

2. Does this mean the FDA is concerned about the safety of antiperspirants?

The FDA considers antiperspirants safe and effective for use as recommended; otherwise, they would not allow them to be marketed. The caution is directed only to a specific segment of consumers with advanced chronic kidney disease and relates to the aluminum used as an ingredient in antiperspirants.

Aluminum has been used safely in antiperspirants for over 100 years. However, since the kidneys play an important role in eliminating aluminum from the body, the FDA decided it was prudent to alert consumers who have kidney disease to the fact that their exposure to aluminum from use of antiperspirants might need to be discussed with their doctor.

3. Can your body absorb the aluminum in antiperspirants?

Aluminum is one of the most abundant elements in the environment. We are exposed to it every day from the food and water we consume and the air we breathe. The amount of aluminum absorbed through the skin from antiperspirants has been reported to be significantly less than the average daily exposure from food and water. A review by a noted dermal absorption expert, Dr. Richard Guy (University of Bath, UK) has estimated that daily exposure to aluminum from antiperspirant use could range from as low as 2% up to 50% of the amount absorbed orally (from food & water).

Small amounts of aluminum can be absorbed from the gastrointestinal tract and through the skin. Assuming a person has normal kidney function, accumulation of aluminum resulting from exposure to antiperspirants is minimal and has no documented adverse health effects. However, people with advanced chronic kidney disease (approximately 30% or less of their original normal kidney function) may have impaired ability to excrete aluminum, resulting in higher levels in the body.

4. How does the FDA define “kidney disease” and how do I know if this warning applies to me?

The FDA does not specifically define “kidney disease” in the June 2004 regulation that required the label.

Kidney experts (nephrologists) at the American Society of Nephrology have reviewed this matter and recommend that patients with advanced chronic kidney disease (i.e., Stage 4 or Stage 5 chronic kidney disease; those patients with approximately 30% or less of original normal kidney function) should talk to their doctors before using an antiperspirant product.

However, we suggest that you consult with your doctor if you have any doubts about whether this warning applies to you.

5. Do all antiperspirants on the market contain aluminum?

Yes. The only active ingredients approved by the FDA for use in antiperspirants all contain aluminum. The concentrations of aluminum in marketed antiperspirants are within the limits allowed by the FDA.

6. What purpose does aluminum serve in antiperspirants?

Aluminum salts form temporary gel plugs in the sweat ducts that stop sweat from being secreted.

7. Why can't manufacturers produce antiperspirant products without aluminum?

The only active ingredients approved by the FDA for use in antiperspirants all contain aluminum.

8. This is just the latest in a string of potential safety issues related to antiperspirants (e.g., Alzheimer's, breast cancer). Isn't this evidence that there really are safety concerns related to antiperspirants?

Absolutely not. There is no convincing scientific evidence that supports an association between Alzheimer's Disease or breast cancer and antiperspirant use. The FDA recently reviewed all available data regarding aluminum and considers antiperspirants safe and effective for use as recommended. The new caution affects only a very specific segment of consumers who have significantly impaired kidney function.