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Warnings on Three Zicam Intranasal Zinc Products

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On June 16, 2009, the Food and Drug Administration (FDA) warned consumers to stop using and discard three zinc-containing Zicam intranasal products. The products may cause a loss of sense of smell.

Intranasal products are administered through the nose.

What products are affected by this warning?

FDA's action affects Zicam's three intranasal products that contain zinc. The three Zicam products claim to reduce the duration of the common cold and the severity of cold symptoms.

The products (listed with their size and product numbers) are

- Zicam Cold Remedy Nasal Gel (15mL, NDC 62750-003-10)
- Zicam Cold Remedy Swabs (20 swabs, NDC 67250-003-20)
- Zicam Cold Remedy Swabs, Kids Size (20 swabs, NDC 67250-003-21)

The Zicam intranasal zinc products are widely sold in pharmacies, other retail stores, and on the Internet. Zicam Cold Remedy Swabs, Kids Size, has already been discontinued, but FDA is concerned that consumers may have the product in their home. FDA has special concerns regarding use of intranasal zinc in children. Children may experience a loss of sense of smell but may be less likely to communicate the condition.

Are oral zinc products affected by this warning?

No. This warning does not involve oral zinc tablets and lozenges taken by mouth.

Dietary zinc is also not subject to this warning. Zinc is an important trace mineral that is an essential part of the human diet. Among other things, Zinc is needed for a healthy immune system (the body's defense), and is critical for normal growth. Zinc primarily comes from food. The best way to get the daily requirement of essential vitamins and minerals is to eat a balanced diet that contains a variety of foods.

Why did FDA take action?

The agency has received more than 130 reports of anosmia—the loss of sense of smell—associated with use of these three Zicam products.

Many people who experienced a loss of sense of smell say that the condition occurred with the first dose, although some people have reported loss of sense of smell after later doses. FDA is concerned that the loss of sense of smell may be permanent.

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What steps did FDA take?

- FDA issued a public health advisory warning consumers to stop using and discard or return the Zicam zinc-containing intranasal products.
- The agency sent a warning letter to Matrixx Initiatives advising the firm that these products cannot be marketed without FDA approval. The warning letter also states that the products do not include adequate warnings about the risk of loss of sense of smell.

What should consumers do if they experience harm related to these products?

FDA recommends they contact their health care professional if they experience loss of sense of smell or other problems after using any zinc-containing products that are administered into the nose.

The agency asks health care professionals and consumers to report possible cases of loss of sense of smell or other problems after use of these products to FDA through the [MedWatch](#) program, either online or by phone at 1-800-FDA-1088.

This article appears on [FDA's Consumer Updates page](#), which features the latest on all FDA-regulated products.

Date Posted: June 16, 2009

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For More Information

- [FDA Advises Consumers Not To Use Certain Zicam Cold Remedies](#)
- [Information on Zicam Cold Remedy Nasal Gel, Zicam Cold Remedy Nasal Swabs, and Zicam Cold Remedy Swabs, Kids Size](#)
- [How to Dispose of Unused Medicines](#)

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