
Posted on Thu, Feb. 02, 2006

Suits say nasal gel stops more than colds

By Virginia A. Smith
Inquirer Staff Writer

Imagine a world without the aroma of morning coffee or buttery popcorn.

Hundreds of people around the country blame a common over-the-counter cold remedy for taking that joy from them: Zicam nasal gel, which is designed to ease the symptoms and shorten the duration of colds.

Last month, Matrixx Initiatives Inc. of Phoenix, maker of the popular Zicam products for colds, flu, sinuses and allergies, agreed to pay \$12 million to settle lawsuits involving 340 plaintiffs. They said they suffered anosmia, or smell loss, after using the zinc-based gel, which is put into the nose with a pump.

The firm admitted no wrongdoing and vowed to continue to "vigorously defend itself" in court. Sixty-one additional cases are pending, some involving Zicam's nasal swabs. The company's sprays and lozenges are not at issue.

No plaintiffs or attorneys returned phone calls over the last week.

Matrixx spokesman Robert J. Murphy said the company had spent \$12 million in legal fees since the first Zicam product-liability suit was filed about 2 1/2 years ago. He called the settlement, announced in the midst of cold season, "strictly a business decision."

And business is good. Matrixx's net sales rose 40 percent to more than \$46 million for the nine months ending Sept. 30, 2005, compared with the same period in 2004.

The firm makes 22 products in the \$3.5 billion retail cough and cold category and says its nasal gel is the only one on the market. Last year, Matrixx introduced a new, gentler spray tip to replace the pump, but the pump is still on shelves in the Philadelphia region.

Zicam products are widely considered "alternative," rather than mainstream, and are classified by the Food and Drug Administration as homeopathic remedies. That means they can be marketed as drugs but are held to a lower standard for safety and effectiveness.

As alternatives grow in number and popularity, that oversight difference becomes increasingly controversial.

Despite repeated requests for details of Zicam users' complaints, spokeswoman Laura Alvey said only that "the FDA continues to monitor and review reports. If the situation warrants, the agency will take proper regulatory action."

'Do not sniff up gel'

According to the FDA's adverse-event database, 133 Zicam users reported having problems in 2004, the latest year available. Most involved the nasal gel and loss of smell, but because smell heavily influences taste, these

people likely also suffered taste loss.

Zicam directions say to place the tip of the pump or swab just inside the nostril, apply the gel, and press lightly on the outside for about five seconds. "To avoid possible irritation," the pump box says, "do not sniff up gel."

Matrixx says that company-sponsored research has never produced any safety concerns and that smell loss can be caused by many things, including some of the conditions Zicam is supposed to treat: bad cold or flu and chronic sinus disease, as well as age, chemotherapy, nasal obstructions and head trauma.

The company blames its legal troubles on Bruce W. Jafek, an ear, nose and throat specialist at the University of Colorado School of Medicine, who in 2003 reported seeing 10 Zicam gel patients who had lost their sense of smell.

Since then, Jafek said in an interview, 100 more patients have contacted the medical school's Rocky Mountain Taste and Smell Center. Zicam gel is used by millions of consumers, "so the loss of smell is relatively uncommon," he said, "but for the person who has it, it's devastating."

Facing off

Matrixx dismisses Jafek's work as unscientific and unsupported by its own experts and studies. In 2004, as one indication of how high this fight's stakes are, the company also announced that it had "discovered that Dr. Jafek's son [who worked in the investment field at the time] 'sold short' shares of the company's stock" just before Jafek's findings were presented.

Matrixx spokesman Murphy last week stopped short of saying father and son had conspired to cause the company's stock price to fall, so they could profit. "It's the reader's job to connect the dots," he said.

Jafek called the allegations "disappointing" and "very close to slander." He said his information "was presented to the scientific community and published in peer-reviewed literature.

"The science is good," he said, adding that other researchers had reported loss of smell in patients using the zinc gel.

Nor was Jafek the first to take note. In the 1930s, Canadian doctors gave intranasal zinc sulfate to 5,000 children in an effort to stop the spread of polio. Some lost their sense of smell in the process. Matrixx says that zinc sulfate is not the same as Zicam's zinc gluconate.

Beverly A. Cowart, clinical director of a taste and smell clinic run by Philadelphia's Monell Chemical Senses Center and Thomas Jefferson University Hospital, said three patients evaluated at the center reported a severe burning sensation, then loss of smell, immediately after using the Zicam gel pump.

Most patients do not have as direct a link.

"They've used the product," Cowart said, "and at some point they weren't smelling very well. Having heard about Zicam, they think maybe it's that."

She said that she had been using Zicam nasal gel for four years, along with her husband and teenage son, and that she believed it had kept their colds from blossoming. "But I can't tell you how much is placebo effect," she said.

She said she suspected that many who had problems were not following directions. "You're supposed to squeeze the pump gently on the edge of the nose," she said, "but it's a pump, and it pumps pretty far."

To cause damage, the gel has to travel through the nasal cavity and reach the brain cells that govern smell. Jafek and other researchers say their patients used the product correctly, while Matrixx maintains it is physically impossible for the gel to get up there.

Whatever the cause, some who have lost their ability to smell may eventually regain some of it. Even so, life might never be the same.

"They can tell there's perfume in the air," Cowart said, "but they can't tell what it is."

Contact staff writer Virginia Smith at 215-854-5720 or vsmith@phillynews.com.