



FDA News

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Advanced Medical Optics Voluntarily Recalls Complete MoisturePlus Contact Lens Solution

The U.S. Food and Drug Administration is alerting health care professionals and their patients who wear soft contact lenses about a voluntary recall of Complete MoisturePlus Multi Purpose Solution manufactured by Advanced Medical Optics of Santa Ana, Ca.

The company is taking this action as a precaution because of reports of a rare, but serious, eye infection, *Acanthamoeba* keratitis, caused by a parasite. The link between the solution and the infection was identified as a result of an investigation by the Centers for Disease Control and Prevention (CDC).

Consumers who wear soft contact lenses should stop using the solution, discard all partially-used or unopened bottles and replace their lenses and storage container.

"We believe the company acted responsibly in taking this voluntary action and support their decision to be proactive in the interest of public health," said Daniel Schultz, M.D., director of FDA's Center for Devices and Radiological Health. "FDA and CDC are working closely with the company to collect additional information and we will continue to alert consumers and advise them as more information becomes available."

Acanthamoeba keratitis may lead to vision loss with some patients requiring a corneal transplant. The infection primarily affects otherwise healthy people who wear contact lenses.

Consumers should ask their doctor about choosing an appropriate alternative cleaning/disinfecting product and seek immediate treatment if they have symptoms of eye infection as early diagnosis is important for effective treatment. The symptoms of *Acanthamoeba* keratitis can be very similar to those of other more common eye infections and may include eye pain or redness, blurred vision, light sensitivity, sensation of something in the eye or excessive tearing but *Acanthamoeba* is more difficult to treat.

It is estimated that *Acanthamoeba* keratitis infections occur in approximately 2 out of every 1 million contact

lens users in the United States each year. However, in a multi-state investigation to evaluate a recent increase in *Acanthamoeba* keratitis cases, CDC determined that the risk of developing AK was at least seven times greater for those consumers who used Complete MoisturePlus solution versus those who did not. Additional information regarding the CDC results is available at the CDC website <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm56d526a1.htm>.

"The ongoing CDC investigation is a collaborative effort," said Michael Beach, M.D., a Division of Parasitic Diseases team leader with CDC. "We are working with FDA, state, territory, university, and clinical partners in an effort to further understand whether usage or contamination of this solution led to these *Acanthamoeba* infections."

All contact lens users should closely adhere to the following measures to help prevent eye infections:

- Remove contact lenses before any activity involving contact with water, including showering, using a hot tub, or swimming.
- Wash hands with soap and water and dry them before handling contact lenses.
- Clean contact lenses according to manufacturer guidelines and instructions from an eye care professional.
 - Use fresh cleaning or disinfecting solution each time lenses are cleaned and stored. Never reuse or top off old solution.
 - Never use saline solution and rewetting drops to disinfect lenses. Neither solution is an effective or approved disinfectant.
- Schedule regular eye exams with your eye care professional
- Wear and replace contact lenses according to the schedule prescribed by your eye care professional.
- Store lenses in a proper storage case.
 - Storage cases should be irrigated with sterile contact lens solution (never use tap water) and left open to dry after each use.
 - Replace storage cases at least once every three months.

FDA and CDC want to gather information related to *Acanthamoeba* keratitis in contact lens users. Report adverse events related to these products to MedWatch, the FDA's voluntary reporting program: www.fda.gov/medwatch/report.htm; Phone: (800) 332-1088; Fax: (800) 332-0178; Mail: MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD, 20852-9787.

Consumers who believe they are in possession of the recalled product may call the company at 1-888-899-9183.

Additional information about *Acanthamoeba* infection is available from the CDC website at <http://www.cdc.gov/ncidod/dpd/parasites/acanthamoeba/index.htm>.

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