



May 25, 2007

Dear Consumer:

Advanced Medical Optics (AMO) has announced a voluntary recall of its Complete[®] MoisturePlus[™] contact lens solutions products. The recall is being initiated because of concerns over eye infections from *Acanthamoeba*, a naturally occurring water-borne organism which can contribute to serious corneal infections.

There is no evidence to suggest that today's voluntary recall is related to a product contamination issue and this does not impact any of AMO's other contact lens care products, including our family of hydrogen peroxide disinfecting solutions.

The U.S. Centers for Disease Control and Prevention (CDC) made data available to AMO today showing that it had interviewed 46 patients who had developed *Acanthamoeba* keratitis (AK) infections reported since January 2005. A total of 39 of these patients were soft contact lens wearers, 21 of whom reported using Complete[®] MoisturePlus[™] products. The CDC estimates a risk of at least seven times greater for those who used Complete[®] MoisturePlus[™] solution versus those who did not. This recall is being conducted on a voluntary basis, in cooperation with the U.S. Food and Drug Administration (FDA).

The incidence of AK infections in the United States has been estimated by CDC at approximately one to two cases per million contact lens users. *Acanthamoeba* is an organism commonly found in water, soil, sewage systems, cooling towers, and heating/ventilation/air conditioning (HVAC) systems. AK infections are usually found among individuals who improperly store/handle/disinfect their lenses (e.g., use tap water or homemade solutions for cleaning), swim/use hot tubs/shower while wearing lenses, come in contact with contaminated water, have minor damage to their corneas, or have previous corneal trauma.

Our first priority is protecting patients' vision and health. We remain fully committed to providing you with products that meet the highest standards for sterility, product effectiveness and patient safety. We are fully cooperating with the CDC and the FDA to meet these goals, and sincerely apologize for any inconvenience this action may have caused you as a user of our products.

If you are a contact lens wearer and have any of these symptoms, you should consult with your eye doctor: eye pain, eye redness, blurred vision, sensitivity to light, sensation of something in the eye, and excessive tearing. The symptoms, which can last several weeks to months, are not the same for everybody. Early in the infection, the symptoms of AK can be very similar to the symptoms of other more common eye infections but AK may eventually cause severe pain and possible vision loss with some patients requiring a corneal transplant, if untreated.

If you use Complete[®] MoisturePlus[™] contact lens solutions products, please follow these steps:

1. Check to ensure that the COMPLETE product you have purchased is a Complete[®] MoisturePlus[™] contact lens solutions product. This recall only pertains to Complete[®] MoisturePlus[™] contact lens solutions products; all other COMPLETE products remain unaffected.
2. If you are using a Complete[®] MoisturePlus[™] contact lens solutions product please discontinue use immediately and call 1-888-899-9183.

3. If you have used a Complete® MoisturePlus™ contact lens solutions product and are experiencing any problems with your eyes, consult your eye care practitioner immediately.
4. Please report any adverse reactions experienced with the use of this product and/or quality problems to AMO by call 1-800-347-5005 and to the FDA's MedWatch Program by phone at 1-800-FDA-1088, or by fax at 1-800-FDA-0178, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch Web site at www.fda.gov/medwatch.

AMO has a 50-year heritage built on high safety and efficacy standards for our products. We are committed to protecting the trust eye care professionals and consumers place in our products and will take all necessary measures to ensure that our products remain safe and effective for the daily disinfecting of all contact lenses.

U.S. CONSUMERS CALL: 1-888-899-9183
(In Canada, call: 1-866-492-6019)

FREQUENTLY ASKED QUESTIONS

Why is AMO recalling product?

AMO is immediately and voluntarily recalling its Complete® MoisturePlus™ (MoisturePlus) in response to information provided Friday (05/25/2007) by the U.S. Centers for Disease Control and Prevention (CDC) regarding eye infections from *Acanthamoeba*, a naturally occurring water-borne organism which can contribute to serious corneal infections. The CDC made data available to AMO showing that it had interviewed 46 patients who had developed *Acanthamoeba* keratitis (AK) infections reported since January 2005. A total of 39 of these patients were soft contact lens wearers, 21 of whom reported using MoisturePlus multipurpose solution.

Is the MoisturePlus multipurpose solution contaminated with *Acanthamoeba*?

No. The CDC analysis indicated that there was no evidence of contamination. All of our products – including MoisturePlus multipurpose solution – have always met and continue to meet all FDA requirements. MoisturePlus multipurpose solution does what it is designed and approved to do.

What is *Acanthamoeba*?

Acanthamoeba is found almost anywhere where there is water – bath water, swimming pools, oceans, lakes, soil, sewage systems, cooling towers, and heating/ventilation/air conditioning systems. AK is a rare, but serious, infection of the cornea that typically affects contact lens wearers.

How do people get AK?

About 85% of AK cases are among contact lens wearers, according to the CDC. People who improperly store, handle, or disinfected their lenses (e.g., by using tap water or homemade solutions for cleaning) or were swimming, using hot tubs, or showering while wearing lenses, are at increased risk for infection.

What are the symptoms of AK?

AK is a rare, but serious, infection of the cornea. Contact lens wearers should consult with their eye doctor if they have any of the following symptoms: eye pain, eye redness, blurred vision, sensitivity to light, sensation of something in the eye, and excessive tearing. The symptoms, which can last several weeks to months, are not the same for everybody. Early in the infection, the symptoms of AK can be very similar to the symptoms of other more common eye infections but AK may eventually cause severe pain and possible vision loss with some patients requiring a corneal transplant, if untreated.

Don't multipurpose solutions kill *Acanthamoeba*?

No multipurpose solution on the market today is specifically formulated to effectively kill *Acanthamoeba*. The vast majority of contact lens users can typically avoid AK by following the recommendations of eye care professionals and lens manufacturers with respect to contact lenses handling and disinfection.

Does this recall pertain to all AMO eye care products?

No. This recall includes only our MoisturePlus multipurpose solution. This does not impact any of AMO's other contact lens products, including our family of hydrogen peroxide disinfecting solutions.

What should someone do if they have a bottle of MoisturePlus multipurpose solution?

If someone has a bottle of MoisturePlus multipurpose solution, they should discontinue use of the product and call **1-888-899-9183** for information on how to return the bottle to AMO for reimbursement.

What should someone do if they already used MoisturePlus multipurpose solution?

AMO recommends discontinuing use of the product and contacting the consumer hotline at **1-888-899-9183** for information about returning the product for a refund. Anyone who believes they are experiencing any problems with their eyes should consult their eye doctor immediately.

Why is there still MoisturePlus multipurpose solution on the shelves in some stores?

AMO is working as quickly as possible since initiating this recall late Friday evening (05/25/07) to provide details to retailers about removing product from shelves and returning it to the company.

Should someone go to the doctor if they've used MoisturePlus multipurpose solution?

Contact lens wearers should consult with their eye doctor if they experience any of the following symptoms: eye pain, eye redness, blurred vision, sensitivity to light, sensation of something in the eye and excessive tearing.

How do consumers get reimbursed?

AMO is working diligently to set up a process for proper reimbursement. Consumers should call **1-888-899-9183** Monday through Friday (Eastern Time) between 8 a.m. and 5 p.m. or visit www.amo-inc.com for additional information.

What do retailers do with stock of the product?

Retailers should immediately remove MoisturePlus multipurpose solution from store shelves. Retailers will receive specific instructions from AMO regarding processes for returning stock and should call **1-888-899-9183** if they have questions.