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## **Advice for Patients With Soft Contact Lenses: Acanthamoeba Keratitis Infections Related to Complete® MoisturePlus Multi Purpose Contact Lens Solution**

May 31, 2007

Dear Contact Lens Wearer,

FDA has learned of a recent increase of a rare but serious infection in people who wear soft contact lenses. The infection is *Acanthamoeba* keratitis, caused by a parasite that is commonly found in nature. It can cause a permanent loss of vision that can require corneal transplants, a surgical procedure to replace the clear outer covering of the eye. Early diagnosis of *Acanthamoeba* keratitis is important for treatment.

The Centers for Disease Control and Prevention (CDC) has confirmed 138 cases of *Acanthamoeba* keratitis in 35 different states. CDC has found an association between this infection and use of the Advanced Medical Optics (AMO) Complete® MoisturePlus Multi Purpose Solution, although at present nothing suggests that the product is contaminated.

Until more information becomes available, precautions are being taken to protect public health. On May 26, 2007, Advanced Medical Optics (AMO) voluntarily recalled all Complete® MoisturePlus Multi Purpose Solution. This means the company is removing all Complete® MoisturePlus Multi Purpose Solutions from store shelves. **AMO is recommending that consumers stop using Complete® MoisturePlus Multi Purpose Solution immediately.**

Investigations by CDC, FDA, state and local health departments, and AMO are underway to define specific behaviors or products that place contact lens wearers at increased risk for *Acanthamoeba* keratitis.

### **Recommendations for users of Complete® MoisturePlus Multi Purpose Solution**

- **Remove your lenses and stop using Complete® MoisturePlus solution immediately.**
- Contact AMO at 1-888-899-9183 for instructions on what to do with unused solution.
- Replace your contact lenses and storage case.
- Ask your eye care professional about choosing another appropriate alternative cleaning/disinfecting product.

### **Safety tips for all contact lens wearers:**

- See your eye care professional immediately if you experience symptoms of eye infection such as redness, pain, excessive tearing, increased light sensitivity, blurry vision, and/or sensation of something in the eye.
- Wear and replace your lenses according to the schedule prescribed by your eye care professional.
- Remove your lenses before any activity involving water, including showering, using a hot tub, or swimming.
- Wash your hands with soap and water, and dry them before handling your lenses.
- Clean your lenses according to the manufacturer's guidelines and instructions from your eye care professional.

- Use fresh cleaning or disinfecting solution each time your lenses are cleaned and stored.
- Never reuse or top off old solution.
- Never use saline solution and rewetting drops to disinfect your lenses. Neither solution is an effective or approved disinfectant.
- Ask your eye care professional if you should use a rub and rinse lens cleaning method rather than a no rub cleaning method.
- Store your lenses in the proper storage case.
  - Rinse your storage case with sterile contact lens solution (never use tap water) and leave the storage case open to dry after each use.
  - Replace storage cases at least once every three months.

More information about contact lenses and eye care can be found at <http://www.fda.gov/cdrh/contactlenses/>.

If you have any concerns about your contact lenses, you should contact your eye care professional.

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

If you have questions about AMO's market recall contact FDA's Division of Small Manufacturers, International and Consumer Assistance at 1-800-638-2041. For consumer information, select # 2.

Additional information on this topic for healthcare providers can be found at: <http://www.fda.gov/cdrh/safety/053107-acanthamoeba.html>

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