

FDA SAFETY ALERT
HOMEMADE SALINE SOLUTIONS FOR CONTACT LENSES

January 24, 1989

To Eye Care Professionals:

This is to ask your help in alerting patients to the hazards of improperly using homemade saline solution in caring for contact lenses. Although you might not recommend the use of homemade saline solutions some of your patients may be using them despite your recommendations. These patients need to know that improper use can result in serious infections that could cause blindness.

PROBLEM

Homemade saline solutions, generally prepared by dissolving salt tablets or capsules in distilled water, are non-sterile and may be contaminated with such pathogenic microorganisms as bacteria and *Acanthamoeba*. These solutions can be safely used in the heat disinfection of contact lenses because the high temperatures are sufficient to kill the organisms.

But if homemade saline solutions are use improperly- that is, as a rinse or eyedrop AFTER heat disinfection, or with chemical disinfection of the lenses-serious infections can result. (It has been shown that some chemical disinfection systems do not kill certain species of *Acanthamoeba*.) In July 1987, the Centers for Disease Control reported on a case-control study that showed an association between the use of homemade saline solutions and *Acanthamoeba* infections (JAMA, July 3, 1987, pp. 57-60). Although this infection represents only a small proportion of all ocular infections, it is a very painful and debilitating condition that is difficult to treat and may lead to blindness.

Homemade saline is only one source of *Acanthamoeba* infection. *Acanthamoebae* are ubiquitous in the environment and have caused eye infections among non-contact lens wearers. However, the recent increase in reported infections among soft contact lens wearers has elevated the concern of the ophthalmic community and the Food and Drug Administration (FDA).

RECOMMENDATIONS

To address this problem, FDA is requesting stronger warnings on salt tablet and salt capsule containers. But we also need your help in changing patient behavior. Because eye care professionals exert considerable influence on patients, we are asking that you convey these important warnings to your patients.

- Use homemade saline solutions only BEFORE or DURING HEAT disinfection.
- Never use AFTER heat disinfection.
- Never use with CHEMICAL or hydrogen peroxide disinfection.
- Never use in the eye or as a wetting solution.

- Prepare fresh saline solution daily.
- Sterilize solution bottle with boiling water at least once a week.

We have included these messages for patients on the attached page, which you may copy and distribute (using your own letterhead or address stamp if you wish).

Thank you for your help in this important effort. If you have comments or questions please contact Richard E. Lippman O.D., F.A.A.O, Director of our Division of Ophthalmic Devices at 8757 Georgia Avenue, Room 440, Silver Spring, MD 20910.

Sincerely yours,

John C. Villforth
Director
Center for Devices and
Radiological Health

SAFETY ALERT: FOR TABLET USERS

Homemade saline solutions (salt tablets or capsules dissolved in distilled water) can cause **SERIOUS EYE INFECTIONS LEADING TO BLINDNESS** if used improperly. In order to avoid such infections you must **FOLLOW THESE DIRECTIONS:**

- Use homemade saline only **BEFORE** or **DURING HEAT** disinfection.
- Never use homemade saline **AFTER** heat disinfection.
- Never use homemade saline with **CHEMICAL** disinfection including hydrogen peroxide.
- Never use homemade saline as an **EYE DROP** or for **WETTING** your lenses.
- Fresh homemade saline should be prepared each day and discarded after use.

When can I use Homemade saline?

Homemade saline can be used for rinsing your lenses **BEFORE** putting them into the heat disinfection unit. You can also use homemade saline in the lens case before you put it in the heating unit

Why can't I use homemade saline after heat disinfection, or as an eyedrop, or for wetting the lenses before I put them in my eyes?

The distilled water used to make homemade saline solutions isn't sterile. It's often contaminated with harmful microorganisms. Homemade saline can be used before or during the heat disinfection process because the high temperature will kill the microorganisms. But if you put homemade saline on your lenses AFTER heat disinfection, the microorganisms can get on your lenses and begin an infection in your eye. If you want to rinse your lenses after heat disinfection you must purchase a preserved or nonpreserved STERILE saline solution.

Why shouldn't I use homemade saline with chemical disinfection?

Chemical disinfection will kill most of the microorganisms normally found on contact lenses. However, unlike heat disinfection, it does not always kill *Acanthamoeba*, which has been found to contaminate homemade saline solutions. *Acanthamoeba* is an organism which can cause a rare but very serious eye infection which is extremely difficult to treat and which has caused blindness.

What else can I do to avoid eye infections?

- Don't swim or use a hot tub while wearing contact lenses. If you accidentally do swim with your lenses on, disinfect them immediately afterwards.
- Always wash your hands before handling your lenses and disinfect soft lenses EVERY TIME THEY ARE REMOVED. Clean and air dry your contact lens case between uses.
- If you use homemade saline, use distilled water (**not tap water**) prepare fresh solution daily following instructions provided, and sterilize your solution bottle with rapidly boiling water for 10 minutes at least once a week.
- If discomfort, pain, discharge, blurred vision, redness or excessive watering occur, remove lenses immediately and consult your doctor.