

Painful Eye Injuries Due To Improper Use Of Hydrogen Peroxide Solutions For Cleaning And Disinfecting Contact Lens

Michael R. Cohen

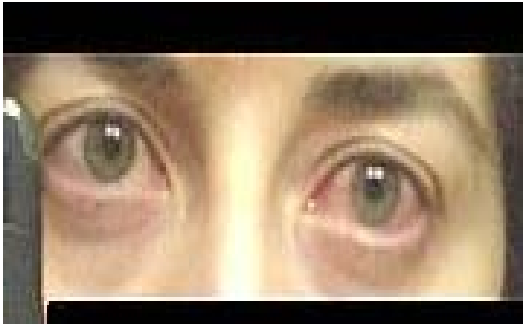
RPh, MS, ScD (hon), DPS (hon), FASHP

President, Institute for Safe Medication Practices



“Yesterday I was putting on my contacts, and after putting my contact lens into my right eye, I immediately had the most excruciating pain and burning I had ever felt in my life.”





ISMP National Medication Errors Reporting Program (ISMP MERP)



Medication Error Reporting Program
Consumer Error Reporting Program
Vaccine Error Reporting Program



Copy of MERP_clear_care(updated 10-11-2016).xlsx [Read-Only] - Excel

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	A	B	C	D	
07	69164	6/20/2016	I accidentally reached for the Clear hydrogen peroxide lens cleaner instead of my regular saline solution rinse. I even looked at the bottle thinking I was making sure it was the correct solution. Being nearsighted, I could barely make out the words but thought I read Clear solution and thought I had the correct bottle. I rinsed my lens and had it nice and wet for insertion. I could not believe the pain. What is worse, my eye clamped shut and I could not open it to remove the lens. I had to pry me eye open and splash it with water before I could even open my eye enough for removal. It burned all day. This is the second day and my vision in that eye is significantly worse. The bottle should be an entirely different shape. It is identical to my saline solution bottle. I never even realized the lid was red. Prevention description: Completely different bottle design. Screw-top lid. People with vision loss use this product. The bottle should not be identical to saline solution.	CLEAR CARE	
08	69165	6/19/2016	My wife used Clear view contact lens cleans in her Lens case. She did not know she had to use the special case with the solution. She placed the lens in her eyes and suffered bilateral eye burns. This solution should not be sold alone. It should have a case with bottle at all times. Warnings on box were not sufficient enough to warn that solution should only be used with special case.	CLEAR CARE	
09	69176	6/22/2016	I bought Clear Care Contact Solution thinking it was a multi-purpose solution that cleaned and disinfected. My usual brand Opti was not available when I got home I open the box and put them on my sink. The next morning I open a bottle without reading because it was by the other contact lens solution and poured it in my right eye. Immediately my eye stung and was on fire. I have not been to the doctor yet but I might loose my eyesight in my right eye. It is swollen almost shut. This is my better eye of the two. I believe that this should only be prescribed and this should not be in the same area of the other multi use formals for contact lens solution.	CLEAR CARE	
10		6/29/2016	Comment: My son accidentally put Clear Care Plus in his eye and is having terrible pain. Besides washing with water, is there anything else he can do?	CLEAR CARE	
11	69205	6/29/2016	4 year old son had sand in his eye and started screaming. I immediately attempted to flush out his eye with the solution I had picked up from the store earlier that morning. I used about 2 drops Clear Care Plus, only to find out, after further screaming, that I hurt his eye more. I immediately checked he bottle and ran into the nearest store to buy Clear Eyes. After flushing his eye out for a few minutes he said he felt much better. However his eye was still red and watery. I checked the packaging closer and saw that it was not regular eye solution. I honestly thought the color of the bottle was simply for design purposes. In regular circumstances I would have read closer, however in a tense situation where I had limited supplies, the labeling was not enough to stop someone from using the product incorrectly.	CLEAR CARE	**was placed in a childs eye
			Clear Care solution by Alcon. I have been wearing contact lenses for 47!years and have never had any packaged identical to the other saline solutions. I use it to clean my lenses and when I put the lends		

clear care

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11		Clear Care solution by Alcon. I have been wearing contact lenses for 47!years and have never had any problem. I recently bought what I thought was same solution because it was shwerved with and packaged identical to the other saline solutions. I use it to clean my lenses and when I put the lends	CLEAR CARE	**was placed in a childs eye

Packaging - Side panels (# turns)



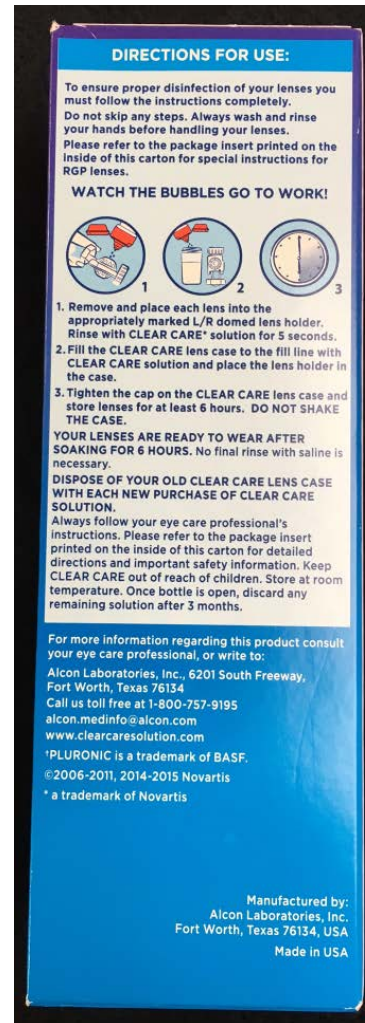
Panel 1

1X



Panel 2

2X



Panel 3

3X



Panel 4

Previous Container



Generic has better warning on box flap

Current Container



Eye drops with red caps



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SPECIAL VALUE! TWIN PACK

CVS
pharmacy™

Compare to Clear Care™

NEW!

HYDROGEN PEROXIDE

CLEANING & DISINFECTING
LENS CARE SYSTEM

3% HYDROGEN PEROXIDE SOLUTION

- For soft (hydrophilic) contact lenses replaced in 30 days or less
- Cleans
- Disinfects
- Removes protein
- Stores



CONTAINS A
CLEANING AGENT

TWO STERILE
12 FL OZ (355 mL) bottles
24 FL OZ (710 mL) TOTAL



**Includes
2 FREE**

Lens cases with
neutralizing disc

SPECIAL VALUE! TWIN PACK

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**Includes
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Lens cases with
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CVS HYD PRX SOL 2P 132
35986 940849 YOU PAY
C01 \$15.49
12/03/15

Inattentional Blindness




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Educating the
healthcare community about
safe medication practices



A nationally certified
Patient Safety Organization




Acute Care

Medication Safety Alert!®

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SafetyBriefs




"2day" gets "86ed" The order below is for SLOW-MAG (magnesium chloride), misspelled as "Slomag," 64 mg TID "2day." The pharmacist questioned whether this

Slomag 64mg TID 2Day

meant to give the medication TID for 2 days (her initial thought) or give it just "today" (2Day). She called to clarify the order, and it turned out that "2Day" was "text messaging" shorthand for "today." The pharmacist asked the nurse to rewrite the verbal order and politely suggested that text messaging language was not appropriate for transcribing medical orders due to potential misinterpretation. Using text messaging abbreviations with medical orders is a new and evolving chapter in the dangerous abbreviations saga.



Product stability for "off label" drug storage. ASHP has a new resource on their website with information on the stability of refrigerated and frozen drugs when not stored according to product labeling. According to ASHP, "it provides useful guidance for emergency preparedness, utility or equipment failure, and improper storage during shipping." The reference, *Stability of Refrigerated and Frozen Drugs*, is available on the Patient Safety Practice Resource Center page under "Recommended Reports" (provided with permission by The Pharmacist's Letter).



Confusing nomenclature. Valproic acid nomenclature can be a little confusing. There are various dosage forms and salts available, so it's easy to understand how products can be confused. That's what happened recently when a physician wrote a prescription for generic divalproex extended release as "divalproex ER" (The International nonproprietary name or INN is valproate semisodium). Actually, the doctor wanted the patient to receive the brand product DEPAKOTE ER, but the hospital's computer system forced prescribers to communicate all prescriptions generically. Later, when a community pharmacist typed in the generic name,

continued on page 2 ▶



Inattentional blindness: What captures your attention?

A nurse pulls a vial of heparin from an automated dispensing cabinet (ADC). She reads the label, prepares the medication, and administers it intravenously to an infant. The infant receives heparin in a concentration of 10,000 units/ml, instead of 10 units/ml, and dies.

A pharmacist enters a prescription for mefloquine daily into the pharmacy computer. A dose warning appears on the screen. The pharmacist reads the warning, bypasses it, and dispenses the medication as entered. The patient receives an overdose of the medication and dies.

A nurse reaches in the refrigerator for a piggyback antibiotic for her patient. She reads the label, spikes the bag with IV tubing, and administers the medication to her patient. The patient receives a neuromuscular blocking agent instead of the intended antibiotic and dies.

A pharmacy technician labels and delivers an IV infusion to the dialysis unit. The nurse reads the pharmacy label and hangs the bag while preparing her patient for dialysis. The patient receives sterile water for injection instead of 0.9% sodium chloride and dies.

A nurse picks out a prefilled syringe of pain medication for her patient. She reads the label and administers the medication intravenously. The patient receives HYDROMORPHONE instead of morphine and experiences a respiratory arrest.

All of these actual errors, and many more in healthcare and other industries, have happened under similar circumstances: the person performing the task fails to see what should have been plainly visible, and later, they cannot explain the lapse.¹ In many cases, people involved in the errors have been labeled as careless and negligent. But these types of accidents are common—even with intelligent, vigilant, and attentive people. The cause is usually rooted in

inattentional blindness, a condition all people periodically exhibit.¹

How do we process information?

Most mental processing occurs outside of conscious awareness. The amount of information that can be taken in by our senses is limitless. But the brain has very limited resources when it comes to attentiveness. Our senses receive much more information than can possibly be processed at one time. To combat information overload, the brain allows large amounts of information through almost entirely unassimilated, peeling off just a few pieces of selected information for a closer look.²

In deciding what to focus on, the brain scans about 30-40 pieces of information (e.g., sights, sounds, smells, tactile information) per second, until something captures its attention.² Our attention filter selects just a small amount of information to process, and anything leftover gets short shrift. The rest of the information never reaches our consciousness—thus the term inattentional blindness. Unfortunately, the brain is a master at filling in the gaps and compiling an integrated portrait of reality based on just a flickering view.¹

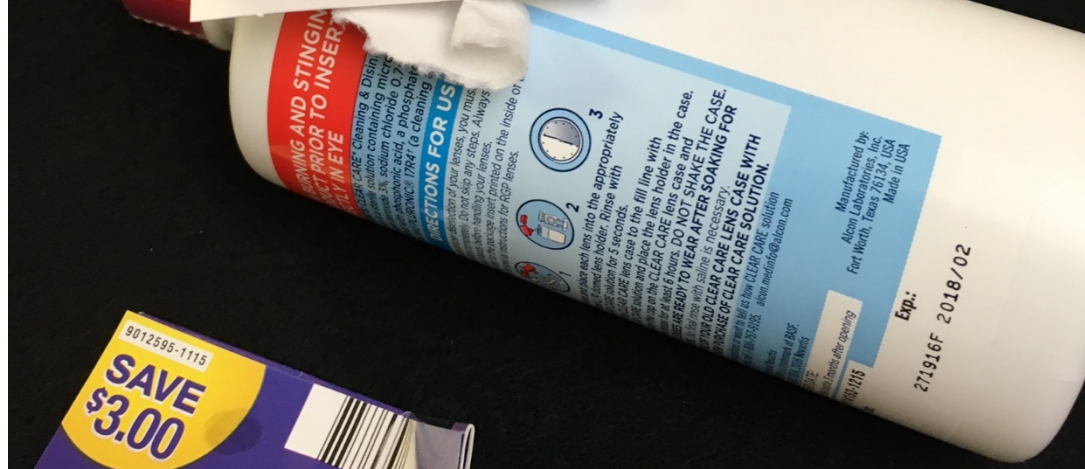
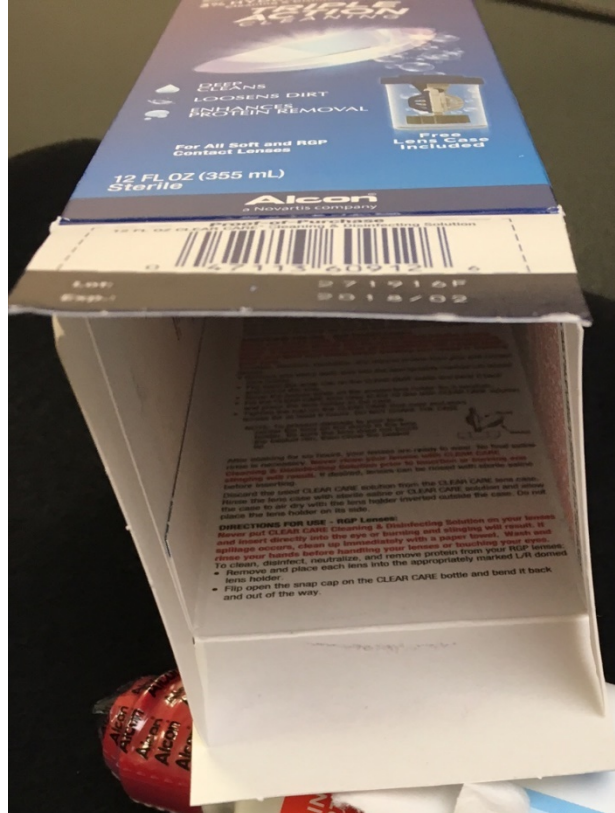
Accidents happen when attention mistakenly filters away important information and the brain fills in the gaps with what is aptly referred to as a "grand illusion."² Thus, in the examples above, the brains of the individuals involved in the errors filtered out important information on medication labels and computer screens, and filled in the gaps with erroneous information that led them to believe they had the correct medication or had read the warning appropriately.

What captures your attention?

Visual attentiveness, or what captures your attention, is shaped by four factors.

Conspicuity. The degree to which an object or piece of information jumps out to capture your attention falls into two categories:

continued on page 2 ▶



SEE PACKAGE INSERT PRINTED ON INSIDE OF CARTON



3% HYDROGEN PEROXIDE Cleaning & Disinfecting Solution

THIS PACKAGE INSERT CONTAINS IMPORTANT PRODUCT USE AND SAFETY INFORMATION. PLEASE READ CAREFULLY AND RETAIN FOR FUTURE REFERENCE.

DESCRIPTION / CONTENTS:

Clear Care® Cleaning & Disinfecting Solution is a sterile solution containing micro-filtered hydrogen peroxide 3%, sodium chloride 0.79%, stabilized with phosphonic acid, a phosphate buffered system, and Pluronic 17R4 (a cleaning agent).

GOOD LENS CARE PRACTICES:

To ensure proper disinfection of your lenses you must follow the instructions completely. Do not skip any steps. Always wash and rinse your hands before handling your lenses. They will help prevent eye infections by removing dirt and oils that could get on the lenses.

DIRECTIONS FOR USE - Soft Lenses:

Do not put Clear Care Cleaning and Disinfecting Solution on your lenses and insert directly into the eye or burning and stinging or redness will result.

TO CLEAN, DISINFECT, NEUTRALIZE, AND REMOVE PROTEIN FROM YOUR LENSES

- Remove and place each lens into the appropriately marked L&R marked lens holder. Rinse with Clear Care for 5 seconds.
- Fill the lens case to fill line with Clear Care and place the lens holder in the case.
- Tighten the cap and store lenses for at least 6 hours or overnight. **DO NOT SHAKE THE CASE.**

NOTE: To prevent damage to your lens, center the lens on the dome in the lens holder. Be sure the lens does not touch the basket rim, then close the basket lid.



After soaking for six hours, your lenses are ready to wear. No final saline rinse is necessary. **Never rinse your lenses with Clear Care Cleaning and Disinfecting Solution prior to insertion or burning and stinging will result.** If desired, lenses can be rinsed with a sterile saline before inserting. Discard the neutralized disinfectant from the cup. Rinse the lens cup with fresh saline or Clear Care and allow the base to air dry with the lens holder inverted outside the case. Do not place the lens holder on its side.

Your eye care professional may recommend additional products such as Uvizyme® Enzymatic Cleaner or procedures to care for your lenses based on individual tear chemistry and lens wearing schedule. Always follow your eye care professional's instructions.

- If your eye care professional recommends use of Uvizyme Enzymatic Cleaner, follow the directions for use on the Uvizyme Enzymatic Cleaner package insert.
- If your eye care professional recommends an additional rubbing step, follow the directions for use for the recommended cleaner prior to using Clear Care.

DIRECTIONS FOR USE - RGP Lenses:

Do not put Clear Care Cleaning and Disinfecting Solution on your lenses and insert directly into the eye or burning and stinging or redness will result.

- Remove your lenses one at a time and place them into the appropriately marked dome basket holder.
- Place each lens in the palm of your hand, apply 2 to 4 drops of Clear Care and rub. While rubbing your lenses with Clear Care, some users may experience a mild, temporary skin discoloration (bleaching) of the fingers or hands. Always wash and rinse your hands after rubbing your lenses with the solution.
- Return the lenses to the appropriate holder and close the baskets. Thoroughly rinse the lenses for 5 seconds through the basket with Clear Care.
- Fill the lens case with Clear Care and place the lens holder in the case. Tighten the cap and store lenses for at least six hours. DO NOT SHAKE THE CASE. Do not rinse the lenses. Place the lenses directly on the eye from the solution or (2) hours.

*According to subjective ratings given by silicone hydrogel lens wearers in a clinical study comparing Clear Care Cleaning and Disinfecting Solution to OPTI-FREE Replenish, OPTI-FREE EXPRESS, Complete MoisturePLUS, and Renu MultiPlus solutions as a group.

place a few drops of a contact lens rewetting drop such as Aquil Long-Lasting Comfort Drops on the lens for extra cushioning.

STORAGE:

If you do not intend to wear your lenses immediately after disinfection/neutralization, you may store them in the unopened lens case for up to 7 days. Disinfect and neutralize once a week with fresh solution and before wearing your lenses.

ACTIONS:

When used as directed Clear Care provides a unique cleaning action which removes film and debris from the lens surface. Clear Care also helps prevent serious eye infections by killing harmful microorganisms on contact lenses.

INDICATIONS (Uses):

For simultaneous cleaning, daily protein removal, disinfecting, and storing of soft hydrophilic or rigid gas permeable (fluoro silicone acrylate and silicone acrylate) contact lenses as recommended by your eye care practitioner.

CONTRAINDICATIONS (Reasons not to use):

There are no known contraindications for use of Clear Care Cleaning & Disinfecting Solution; however, if you are allergic to any ingredient in this solution, do not use.

WARNINGS:

Do not put Clear Care Cleaning and Disinfecting Solution on your lenses and insert directly into the eye. Lenses must be soaked in the provided lens case for 6 hours (neutralization process) prior to lens insertion. OTHERWISE, BURNING AND STINGING WILL RESULT.

Only use the Clear Care Lens Case for disinfection and neutralization. Do not use a flat case.

While rubbing RGP lenses with Clear Care, some patients may experience a mild, temporary skin discoloration (bleaching) of the fingers or hands. Always wash and rinse your hands after rubbing your lenses with the solution.

DO NOT PUT CLEAR CARE SOLUTION THAT HAS NOT BEEN NEUTRALIZED IN YOUR EYE. Should unneutralized Clear Care get in your eye, remove your lenses immediately, flush (wash) your eyes with a large amount of water or sterile saline for a few minutes. If burning and/or irritation persist, seek assistance from an eye care professional. The red dropper tip indicates that Clear Care Cleaning & Disinfecting Solution should not be put directly in your eye.

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. Follow your eye care professional's directions and all labeling instructions for proper use and care of

your lenses and lens care products, which develop rapidly and lead to loss of vision. I worn while sleeping. Clinical studies have shown that wearers of extended wear lenses and replacement on the schedule prescribed an increased incidence of serious adverse contact lens events. Studies have also shown wear lenses are worn before removal for vision changes, or redness of the eye, are extremely important in order to detect and pain.

Replace cap after using. To avoid contamination, all contact lens wearers must see their eye professional. All contact lens wearers should

Studies have shown that smoking increases the risk of eye disease. Do not smoke while wearing lenses.

Do not take Clear Care Cleaning and Disinfecting Solution as a substitute for professional assistance of physician or a poison control center.

PRECAUTIONS:

- Always wash and dry your hands before use.
- Never use this for heat disinfection.
- Never reuse this solution.
- Keep bottle tightly closed when not in use.
- Store at room temperature. (15°C to 30°C)
- Use before the expiration date marked on the label.
- Once bottle is open, discard any remaining solution.

There are no safe, acceptable substitutes for Clear Care Cleaning and Disinfecting Solution. Do not use other lens care hydrogen peroxide solutions as they are not intended for ophthalmic use. Hydrogen peroxide may contain ingredients that are harmful to the eye.

LENS CASE CARE

- To avoid possible damage:
- Do not over tighten the case (only tighten the cap).
- Do not use a damaged lens case.
- Do not fill above the fill line on the case.
- Do not shake the case during disinfection.
- Dispose of your old lens case with each new lens case.

ADVERSE REACTIONS (Possible problems)
The following problems may occur with Clear Care. If you experience any of the following, stop using Clear Care immediately and consult your eye care professional.

- If the problem stops and the lenses appear normal, stop using Clear Care. Do not put the lenses back in your eye.
- If the lens is in any way damaged, do not use it.
- If the lens has dirt, an eyelash, or other foreign matter on it, do not put it back in your eye. Rinse the lens with Clear Care and reinsert it. Do not put Clear Care in your eye.
- If the problem continues IMMEDIATELY stop using Clear Care.

Safety issues

- Patients mistake container for soak or non-peroxide cleaner
- Use their own lens case or sometimes squirt/pour liquid directly into eye
- Painful eye injuries, corneal abrasion (finger nail scratch upon attempt to remove lens from eye)
- Visits to emergency department
- Missed school and work

Safety issues (cont'd)

- Consistently 1-3% of audience has experienced an event, including several ISMP employees (5/30) and my own relatives (do NOT first ask for lens wearers)
- Difficulty seeing and reading warnings when removing lenses for cleaning, not wearing glasses.
- Problems continue despite label revisions, red cap, etc.
- Have been articles in Consumer Reports, FDA Consumer, NBC News, Reuters, ISMP Consumer website and newsletters, Philadelphia Inquirer



Some have recommended that pharmacists isolate stock – Store behind the pharmacy counter

Prevention

- Communicate with ophthalmologists, optometrists and community pharmacists who may not be aware of solution properties and potential adverse events
- Advise contact lens wearers who begin use of lenses
- Improved warnings on container – Currently no warning on front of carton. May cause burning to “May cause severe burning”
- Placement of warning now on panel 4 on primary display panel (#1)

Prevention

- Use of appropriate signal words – “Danger” instead of “Warning,” in appropriate color background. Visible on bottle no matter how turned.
- Simplify container warnings to make easier to read.
- Complete redesign of container (ACT mouthwash example)
 - Bottle shape different than other solutions
 - Special attached lens case with removable lens holders and platinum ring
 - Fill from bottom, no tip for squirting into eye - no need to pour into case
 - Looks different than other types of cleaning solutions, works differently

