FDA Panel Meeting

The Vantage Point of CooperVision’s Peroxide System

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Objectives

- Overview of CooperVision’s Peroxide lenscare System.
  - Known characteristics and efficacy.
  - Known user issues.
- Past product changes.
- Proposed future changes for improvements to include:
  - Product specific changes, particularly labelling.
    - i.e. labelling (quantity reduction, focus on key instructions/warnings, and larger text).
  - Use of a CEP (Compliance Education Program).
  - Product Shelf segregation in retail locations.
  - Future use of QR (Quick Response) Technology & website & links for enhanced product information
  - Possible use of information sharing technologies.
Overview of CooperVision’s peroxide system

Approval History
• One-step peroxide system was approved by Sauflon Pharmaceuticals (UK based CL manufacturer) in 2001 - K010559.
• Marketed through several retail outlets in the USA.
• Sauflon was acquired by CooperVision back in 2014.
Overview of CooperVision’s peroxide system

Key Characteristics and efficacy:
• One-step hydrogen peroxide (H₂O₂) solution is a gold standard for disinfection, effective against a broad range of ocular pathogens (meeting the ISO14729 panel).
• Indicated to disinfect, clean and store lenses.
• Contains H₂O₂ as the active ingredient at 3.0%.
• The solution is neutralised in situ in a specially designed lens case by the inclusion of a specific platinum coated catalytic disk.
Overview of CooperVision’s peroxide system

Known user issues:
• Rinsing of lenses and/or insertion of peroxide directly into the eye causing discomfort, stinging and redness.
• Not using the correct case containing the catalytic disk so the peroxide remains unneutralised.
• Not allowing sufficient time to neutralise the peroxide in the case;
  • at least 6 hours is required.
Past changes for improvement

Past product changes:
• Use of a bright red cap to distinguish from the white cap used on standard Multipurpose solutions (MPS).
• Specific website links to product information and patient user guides.
• Adherence to the latest labelling guidance on the product (FDA, Aug 2010).

What else can we do?
Proposed future changes for improvements

Proposed improvements - Labelling:

- Reduce content of labelling and make it **larger** for patients to easily read.
- Reduce content to Focus only on prominent instructions to make it **clearer** on the labelling to indicate against the known areas of user misuse – **6 key rules to success:**

1. **DO NOT** put the contents of this bottle (hydrogen peroxide) directly into your eye.
2. **DO NOT** put the contents of this bottle (hydrogen peroxide) directly on your lenses and insert directly into your eye.
3. **DO NOT** wear the lenses unless you have allowed them to soak for at least SIX (6) hours in Hydrogen Peroxide Cleaning and Disinfecting Solution using the case provided.
4. **USE ONLY THE NEUTRALISATION LENS CASE PROVIDED**
5. **PLEASE READ AND FOLLOW** the detailed Directions for Use and Important Safety Information provided with the product (leaflet/printed on carton).
6. **DO ALWAYS FOLLOW** your eye care professional’s instructions on how to use the product.
Proposed future changes for improvements

Proposed improvements - Labelling continued:

- Add red box **warning** on top/front face of bottle and carton labelling.

  CAUTION: HYDROGEN PEROXIDE SYSTEM

CAUTION: this bottle contains HYDROGEN PEROXIDE – do not put directly into your eye.

CAUTION: HYDROGEN PEROXIDE – do not put directly into your eye.

- Use of universal diagrams/symbols where possible to reduce the print and language requirements.
Proposed future changes for improvements

Proposed improvements

CooperVision’s Compliance Education Program (CEP).

The purpose of CEP is to:

- Ensure that patients experience a safe, comfortable and satisfying contact lens wearing experience from start to finish.
Proposed future changes for improvements

Proposed improvements
CooperVision’s Compliance Education Program (CEP).

The CEP objectives are to:

- Improve lens care compliance.
- Take a proactive position in educating ECPs, retailers & end users on the importance of Lens Care Product selection and following lens care instructions.
- Partner with ECPs on provision of educational tools/information to educate patients when prescribing frequent replacement lenses (FRP), and care for lenses.
- Provide educational tools for retailers, ECPs and end-users.
Proposed future changes for improvements

Shelf Segregation of Hydrogen Peroxide
Proposed future changes for improvements

Proposed improvements – QR coding

- User Guidance Video with linked QR (quick response) code on labelling linking to a patient guidance video on the CooperVision website.
Proposed future changes for improvements

Generally industry may consider communication Technologies:

**NFC**

Near field communication
Information exchange between two devices

- NFC tags on adverts and posters in shops or in the street can offer you discounts or information based on your preferences by a tap of your phone.

**iBeacons** (Apple’s Version of NFC)

Get In-Store Notifications
Examples of Other Future information sharing options:

- Google - Goggles users can find useful information from a photo. Take a photo of a product, you will then be served results on that object in the same way that a text search would.

- SnapTag - This basically turns your brand’s logo into an adaptable tool, that can be scanned anywhere a user sees it and taken to any marketing message, link or promotion a brand wishes to direct them to.
Our commitment:

We look forward to fully engaging with any initiatives, further discussions, and partnering with FDA on improving the contact lens wearing experience for our patients.
Thank you

Questions?