LENS PLUS® OCUPURE™ SALINE Solution

SCHEDULING STATUS:
Schedule 0

PROPRIETARY NAME
(and dosage form):
LENS PLUS® OCUPURE™ SALINE Solution

COMPOSITION:
LENS PLUS OCUPURE SALINE Solution is a sterile, buffered, isotonic solution containing boric acid and sodium chloride. Stabilised oxychloro complex (OCUPURE) equivalent to 0.005 % m/v stabilised chlorine dioxide.

PHARMACOLOGICAL CLASSIFICATION
A. 34 Other.

PHARMACOLOGICAL ACTION
LENS PLUS OCUPURE SALINE Solution is a solution approximately isotonic with lachrymal fluid.

INDICATIONS
LENS PLUS OCUPURE SALINE Solution is indicated for use with soft (hydrophilic) or rigid gas permeable (RGP) contact lenses. It can be used:
• As a rinsing agent after daily or weekly cleaning of lenses and before lens application
• For storage after heat or hydrogen peroxide disinfection.
• For storage of lenses up to 30 days following disinfection.
• As a diluent for enzymatic tablets designed to be dissolved in saline.

CONTRA-INDICATIONS
LENS PLUS OCUPURE SALINE Solution is contra-indicated in patients with a history of hypersensitivity to any of its components.

WARNINGS
Do not allow your lenses to become dry during storage.

DOSAGE AND DIRECTIONS FOR USE
RINSING
After lens removal
Clean lenses as recommended with an appropriate cleaner. Rinse thoroughly with LENS PLUS OCUPURE SALINE Solution. Proceed with disinfection as recommended.
Before lens application
After disinfection, rinse lenses thoroughly with LENS PLUS OCUPURE SALINE Solution before applying them to your eyes.

DISINFECTING/STORAGE WITH HEAT
• After cleaning and rinsing, place lenses in appropriate chamber of lens case.
• Fill each chamber with LENS PLUS OCUPURE SALINE Solution.
• Place lens case into the heat (thermal) disinfection unit and follow the directions for operating the unit.
• Lenses may be stored in the unopened lens case after the heat disinfecting cycle for up to 30 days. If they are stored for...
longer periods of time, disinfect lenses every 30 days. If they are stored for longer periods of time, disinfect lenses every 30 days again prior to wearing.

STORAGE
• Storage in LENS PLUS OCUPURE SALINE Solution is not a substitute for disinfection.
• LENS PLUS OCUPURE SALINE Solution may be used to store lenses prior to disinfection and up to 30 days following disinfection. If the lenses are stored for longer periods of time, disinfect every 30 days and again prior to wearing.
• When using any hydrogen peroxide system, LENS PLUS OCUPURE SALINE Solution may be used after the hydrogen peroxide has been neutralised.
• Discard the neutralised solution from lens case.
• Rinse and fill the lens case with fresh LENS PLUS OCUPURE SALINE Solution. (If a platinum disc is being used, remove the disc from the lens cup or the stem of the lens holder. Store disc in a second lens holder and cup. Allow to air dry.)
• If lenses are stored longer than the recommended time in the hydrogen peroxide system, they should be cleaned and disinfected again before storing in LENS PLUS OCUPURE SALINE Solution.
• Store below 25°C and protect from light.

DISSOLVING ENZYMATIC PROTEIN REMOVER TABLETS
• Rinse vials and fill to the line with LENS PLUS OCUPURE SALINE Solution.
• Drop one tablet into each vial and allow to dissolve.
• Clean lenses with appropriate cleaner and rinse thoroughly with LENS PLUS OCUPURE SALINE Solution.
• Place lenses in appropriate vials and follow directions for soaking.
• Remove lenses from vials and rinse thoroughly with LENS PLUS OCUPURE SALINE Solution while rubbing lens gently between fingers.
• Proceed with disinfection as recommended.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS
The following problems may occur:
• Eyes stinging, burning, or itching (irritation)
• Excessive watering (tearing) of the eyes.
• Unusual eye secretions.
• Reduced sharpness of vision (visual acuity)
• Blurred vision
• Sensitivity to light (photophobia)
• Dry eyes
If any of the above problems are noticed, immediately remove and examine the lenses. If a lens appears to be damaged, do not reapply; consult the eye care specialist. If the problem stops and the lenses appear to be undamaged, thoroughly clean, rinse and disinfect the lenses and reapply them. If the problem continues, immediately remove the lenses and consult an eye care specialist.
If any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularisation, or iritis may be present. Immediately remove lenses and seek immediate professional identification of the problem and begin treatment, if necessary, to avoid serious eye damage. For more information, see the instructions for wearers’ booklet for the specific contact lenses.

Special precautions
• Always wash and rinse hands thoroughly before handling the lenses.
• If irritation develops, discontinue lens wear and consult your eye care practitioner.
• Always handle the same lens first to avoid any mix-ups
• Do not take solution orally or use for injection.
• Do not touch tip to any surface.
• Use before the expiration date marked on the container.
• To prevent infection, NEVER wet contact lenses with saliva or place lenses in your mouth.
• Always rinse lenses thoroughly after cleaning.
• Do not reuse LENS PLUS OCUPURE SALINE Solution.
• Keep bottle tightly closed when not in use.
• Lenses should be cleaned, rinsed and disinfected each time you remove them.

**IDENTIFICATION**
Clear, colourless, odourless solution, practically free from particulate matter.

**PRESENTATION**
LENS PLUS OCUPURE SALINE Solution is supplied in teal green HDPE bottles, containing 240 ml solution

**STORAGE INSTRUCTIONS**
Store below 25°C.
Discard 90 days after first opening.
KEEP OUT OF REACH OF CHILDREN.

**REGISTRATION NUMBER**
33/34/0002

**NAME AND ADDRESS OF THE APPLICANT**
Genop Healthcare (Pty) Ltd
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SOUTH AFRICA
For Advanced Medical Optics (AMO) Inc. U.S.A.

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