

TOPICAL IRRIGATION SOLUTION 0.9% W/V
(EYE WASH & WOUND IRRIGATION)
PACK INSERT

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PRODUCT NAME

Topical Irrigation Solution 0.9% w/v (Eye Wash & Wound Irrigation)

COMPOSITION

Each ampoule/Bottle contains:
Sodium Chloride Ph. Eur.....0.9% w/v
Water for Injection.....q.s.

INTENDED PURPOSE

Topical Irrigation Solution 0.9% w/v (Eye Wash & Wound Irrigation) is intended for washing the eyes, including providing first aid by helping to remove harmful substances and dangerous liquids like alkali or acids from the eye in emergency situations.

For healthcare professionals, this solution is also used for washing, flushing, or rinsing parts of the body, such as wounds, and for cleaning medical supplies and equipment, including dressings, catheters, and drainage tubes. In emergency first aid situations, it is essential to use this solution under professional supervision to safely remove harmful substances and dangerous liquids from the eye and wounds.

INFORMATION FOR HEALTHCARE PROFESSIONAL AND LAY PERSON

Information	Healthcare Professional	Lay Person
Brand Name	OPTRA-SAFE	LAMO-SAFE
Intended User	Healthcare Professional (Physician and nursing Staff)	Intended to be used by Layperson
User Environment	Intended to be used in healthcare facilities only.	Intended to be used in Homecare setting only.

DEVICE DESCRIPTION

Topical Irrigation Solution 0.9% w/v (Eye Wash & Wound Irrigation) is sterile and nonpyrogenic irrigation solution which is indicated for general irrigation, washing, rinsing parts of the body,irrigation of indwelling urethral catheter and surgical tubes.

INDICATION

HEALTHCARE PROFESSIONAL

- Irrigation (Washing) of the eyes, including first aid and the removal of harmful substances and dangerous liquids, like alkali or acids, from an eye in an emergency first aid situation
- Irrigation of indwelling urethral catheters and surgical drainage tubes
- Irrigation of Intra and postoperative bladder, Irrigation in urological surgical procedure, Irrigation of the gastrointestinal tract, Irrigation of fistulas and drainages, and cleaning of wound dressing and injuries

LAY PERSON

- Washing and flushing or rinsing body cavities, tissues or wounds.

INTENDED PATIENT POPULATION

The device can be used in Children, Adults, & Geriatric population.

SHELF LIFE OF DEVICE

5 years from date of manufacturing Use

DURATION OF USE

Topical Irrigation Solution 0.9% w/v is for short term (between 60 minutes and 30 days)

USAGE FREQUENCY

Single use only

DOSAGE AND ADMINISTRATION

The dose is dependent upon the capacity or surface ar ea of the structure to be irrigated and the nature of the procedure.

PHYSICAL DATA

Physical state – Liquid

Appearance: Clear, colourless liquid

Odour: Odourless

Sterility – Sterile, pyrogen free

OPERATING PRINCIPLE

Topical Irrigation Solution 0.9% w/v (Eye Wash & Wound Irrigation) contains water and sodium chloride, which creates a gentle and effective solution for irrigating and cleaning wounds, eyes, and other parts of the body. Sodium is the major cation of extracellular fluid and functions principally in the control of water distribution, fluid and electrolyte balance and osmotic pressure of body fluids. Chloride, the major extracellular anion, closely follows the physiological disposition of sodium cation in maintenance of acid, base balance, isotonicity and electrodynamic characteristic of the cells. When Topical Irrigation Solution 0.9% w/v (Eye Wash & Wound Irrigation) is applied to the affected area, it helps to flush out any dirt, debris, or bacteria that may be present. This helps to promote healing by reducing the risk of infection and allowing the body's natural healing processes to take place. It is particularly useful for cleaning wounds, including cuts, scrapes, and burns, as well as for washing the eyes in the event of exposure to dust, dirt, or other irritants. The solution's isotonic properties also help to maintain the normal physiological balance of the tissues, which promotes healing and prevents infections.

CONTRAINDICATION

- Topical Irrigation Solution 0.9% w/v (Eye Wash & Wound Irrigation) should not be used during electrosurgical procedures
- Topical Irrigation Solution 0.9% w/v (Eye Wash & Wound Irrigation) should not be used in patients with eye disorders or infections, such as conjunctivitis or those currently wearing contact lenses.
- Patients with congestive heart failure or hypertension should use this solution with caution, as excessive sodium intake can worsen their condition.
- Topical Irrigation Solution 0.9% w/v (Eye Wash & Wound Irrigation) should not be in Patients having urinary tract infection

HOW TO OPEN THE DEVICE

The ampoule shall twist open in one or two turns.

INSTRUCTIONS FOR USE FOR LAY PERSON

- Ensure hands are clean before handling the solution.
- After opening, the solution must be used immediately.
- Pour the solution on the site of application as per the recommended dosage.
- Soak the gauze in the saline solution and gently wipe the wound.
- Once the product's seal is opened, do not store any unused solution. Discard it immediately.
- Used/empty ampoule or bottle should be safely disposed.
- If you have any concerns or questions, consult a healthcare professional.
- Product should be stored at temperature between 2- 32°C and keep way from sunlight.
- For single use only.

INSTRUCTIONS FOR USE FOR HEALTHCARE PROFESSIONAL

- After opening, the solution must be used immediately
- For eye irrigation invert the bottle and direct the nozzle towards the inner corner of the affected eye. Gently squeeze the bottle and tilt the head to allow the saline solution to flow across the affected eye towards the outer corner, repeat until the eye has been thoroughly irrigate
- For catheter irrigation connect tip of the ampoule/bottle with the catheter and empty the contents of the ampoule/bottle into the catheter by squeezing the ampoule/bottle. If there is any minor sediment in the catheter, should be recovered by using mechanical pumping movements with the ampoule/bottle.
- Monitor the patient for any adverse reactions during and after using the product.
- Document the administration process and any patient responses.
- Store the solution as per manufacturer recommendations.
- Used/empty ampoule or bottle should be safely disposed
- For single use only



PRECAUTION

- Do not administer unless solution is clear, seal is intact, packaging and container is undamaged.
- Do not use for irrigation that may result in absorption into the blood.
- Do not use it after the expiry date (EXP) printed on the label.
- Do not use Topical Irrigation Solution 0.9% w/v (Eye Wash & Wound Irrigation) if the packaging is torn or shows signs of tampering.
- Keep out of reach of children
- Discard unused portion.

Tell your doctor if you have any allergies to:

- Any other substances, such as foods, preservatives or dyes

Tell your doctor if:

- you have heart disease
- you have or have ever had problems with your liver or kidneys
- you have swelling of the hands, ankles or feet
- you are pregnant or planning to become pregnant
- you are breastfeeding.
- We have not studied the effect of Topical Irrigation Solution 0.9% w/v (Eye Wash & Wound Irrigation) on pregnant and breast-feeding women. Hence, we do not recommend to use at this moment.
- Before using Isotonic Saline solution 0.9% w/v, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details. Before using this product, tell your doctor or pharmacist your medical history, especially of other eye problems.

WARNINGS

- FOREYE WASH & IRRIGATION ONLY, NOT FOR INJECTION.
- Do not warm above 150°F (66°C).
- After opening container, its contents should be used promptly to minimize the possibility of bacterial growth or pyrogen formation. Discard unused portion of irrigating solution since it contains no preservatives.
- Irrigating fluids have been demonstrated to enter the systemic circulation in relatively large volumes; thus, irrigation solutions must be regarded as systemic drugs. Absorption of large amounts can cause fluid and/or solute overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema.
- The risk of dilutional states is inversely proportional to the electrolyte concentrations of the administered parenteral solutions. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentration.
- Do not resterilize.

SIDE EFFECTS

- Epistaxis
- Otalgia
- Pain
- Eye Burning
- Discomfort
- Temporary blurred vision
- This solution may be absorbed into the blood, especially if it used continuously or if it stays inside your body for a long time. This absorption may cause side effects such as too much fluid in the body. Tell your doctor immediately if any of these unlikely but serious side effects occur: signs of infection (e.g., fever), swelling, unusual weakness, mental/mood changes (e.g., restlessness, irritability). This is not a complete list of possible side effects.

ADVERSE REACTIONS

While systemic overdose would be extremely rare when used as directed, excess sodium chloride in the body may produce gastrointestinal side-effects such as nausea, vomiting, diarrhoea and cramps. Salivation and lacrimation are reduced, whilst thirst is increased. Other possible symptoms include hypotension, tachycardia, headache, dizziness, weakness, muscle twitching or rigidity, peripheral and pulmonary oedema and respiratory arrest.

LIMITATIONS

- Topical Irrigation Solution 0.9% w/v (Eye Wash & Wound Irrigation) it is not effective against certain types of bacteria that can cause infections.
- Potential for irritation: While Topical Irrigation Solution 0.9% w/v (Eye Wash & Wound Irrigation) is generally well-tolerated, some individuals may experience irritation or discomfort when it is applied to the eyes or wounds.
- This device is not intended for parenteral use or for preparations intended for parenteral use.

CLINICAL BENEFITS

Topical Irrigation Solution 0.9% w/v (Eye Wash & Wound Irrigation) improves patient care by providing an effective eye wash for removing harmful substances and dangerous liquids, such as alkalis or acids, in emergency situations. It is used to wash, flush, and rinse wounds, as well as to clean medical supplies and equipment such as bandages, catheters, and drainage tubes. This treatment helps the safe removal of harmful substances from the eyes and wounds under medical supervision, thereby improving emergency first aid and overall hygiene.

CLINICAL PERFORMANCE

- The solution is effective at removing harmful substances or dangerous liquids from the eyes or other parts of the body. It helps to flush out foreign particles, debris, and other irritants from the affected area.
- It can be used to rinse medical equipment such as catheters, drainage tubes, and dressings, to remove debris and other contaminants.

CLINICAL SAFETY

- Topical Irrigation Solution 0.9% w/v is safe for use on various tissues and surfaces, minimizing the risk of damage to tissue.
- Topical Irrigation Solution 0.9% w/v is compatible with most medical supplies and equipment, including dressings, catheters, and drainage tubes. This ensures that it can be used safely in a wide range of medical situations.

KNOWN CHARACTERISTICS OF DEVICE IN CASE OF RE-USE

- Any infectious disease can transfer
- Chances of Cross-contamination

STERILIZATION

Topical Irrigation Solution 0.9% w/v (Eye Wash & Wound Irrigation) supplied in sterile condition

STERILIZATION TYPE

Sterile via Aseptic Processing Technique (2 ml, 2.5 ml, 3ml, 5 ml,10 ml,15 ml, 20 ml ,25 ml, 30 ml ampoule); Moist Heat Sterilization (50 ml, 60 ml, 100 ml,120 ml bottle).

USABILITY & INFORMATION HAZARDS

- Mishandling of the product for package leads to microbial contamination of the device
- Improper removal of device from package leads to product damage & chances of side effects
- Off label use of the product may increase the chances of side effect
- Inadequate Topical Irrigation Solution 0.9% w/v leads to reversible side effects like infection/swelling/restlessness /irritability/unusual weakness

STORAGE & TRANSPORTATION

- The recommended storage temperature is 2-32°C
- Do not freeze.
- Keep away from moisture and direct heat.
- Do not warm above 150°F (66°C).
- Keep away from sunlight.
- Keep dry.
- Do not re-sterilize.
- Discard unused portion.

HOW IS IT SUPPLIED

Small sizes (2 ml, 2.5 ml, 3 ml, 5 ml, 10 ml, 15 ml, 20 ml, 25 ml, 30 ml) are packed in LDPE ampoules, and large sizes (50 ml, 60 ml, 100 ml, 120 ml) are packed in LDPE bottles.

Pack Sizes	Qty in Cassette	Qty in Carton	Total Qty. In Carton
2ml	5	5 X 4	20 Ampoules
2.5ml	5	5 X 4	20 Ampoules
3ml	5	5 X 4	20 Ampoules
5ml	5	5 X 4	20 Ampoules
10ml	5	5 X 5	25 Ampoules
15 ml	5	5 X 5	25 Ampoules
20ml	5	5 X 5	25 Ampoules
25ml	5	5 X 4	20 Ampoules
30ml	5	5 X 4	20 Ampoules
50 ml	2	2 X 6	12 Bottles
60ml	2	2 X 6	12 Bottles
100ml	2	2 X 6	12 Bottles
120ml	2	2 X 6	12 Bottles

DISPOSAL INSTRUCTION

Dispose of the product in accordance with accepted medical practice and applicable local, state and national laws and regulations.

NOTICE TO USERS AND/OR PATIENTS

In the event of malfunction of the device or changes in its performance that may affect safety, or any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

EXPLANATION OF SYMBOLS USED

Name of the Symbol	Symbol	Description of Symbol
Lot No.		Indicates the manufacturer's batch code so that the batch or lot can be identified.
Date of Manufacture		Indicates the date when the medical device was manufactured.
Use by		Indicates the date after which the medical device is not to be used.
Consult Pack Insert		Indicates the need for the user to consult the instructions for use.
Do not reuse		Indicates a medical device that is intended for one single use only.
Do not resterilize		Indicates a medical device that is not to be resterilised.
Do not Use if Package is damaged		Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.
Sterilized using aseptic processing techniques		Indicates a medical device that has been Sterilized using aseptic processing techniques
Non-Pyrogenic		Indicates a medical device that is non-pyrogenic.
Keep Dry		Indicates a medical device that needs to be protected from moisture
Keep away from sunlight		Indicates a medical device that needs protection from light sources
Manufacturer Detail		LEGECY REMEDIES PVT. LTD. Kh. No. 132/2 & 133/2, Village Katha, Baddi, Distt. Solan (H.P.), 173205, INDIA. Phone: +91 09816099295; +91 09817602007. Email: legencyremedies@rediffmail.com Website: www.legencyremedies.com
Manufacturer		To identify the country of manufacture of products
Catalogue No.		Indicates the manufacturer's catalogue number so that the medical device can be identified.
Temperature limit		Indicates the temperature limits to which the medical device can be safely exposed.
Manufacturer Logo		Logo of LEGECY REMEDIES PVT. LTD.
CE Marking		CE mark with the Notified Body number
Unique Device Identifier		Indicates a carrier that contains Unique Device Identifier information
Instructions for Use		This symbol indicates that the accompanying documents must be consulted
Medical Device		Indicates the item is a medical device
Authorized representative in the European Community / European Union		EUROPECERT UG (HAFTUNGSBESCHRÄNKT) Allstr., 97 41063 Monchengladbach, Germany. Tel. +49 21619908831 Email: support@europecert.eu
Importer		To indicate the entity importing the medical device into the locale
Distributor		Distributor Indicates the entity distributing the medical device into the locale
Caution		To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
Single sterile barrier system with protective packaging outside		Indicates a single sterile barrier system with protective packaging outside.