

ISOTONIC SALINE SOLUTION 0.9% W/V

PACK INSERT

Doc No: LR-MDR-IR-PI-03B

Rev No.: 00

Date:01.05.2024

PRODUCT NAME

Isotonic Saline Solution 0.9% w/v

COMPOSITION

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

INTENDED PURPOSE

Isotonic Saline Solution 0.9% w/v is intended to wash, flush, or rinse body cavities, tissues, or wounds, facilitating wound care by cleaning wound dressings and injuries directly or through impregnated gauze pads and dressings. Similarly, for healthcare professionals, this solution has the same purpose, ensuring proper wound care and hygiene by cleaning body cavities, tissues, or wounds and effectively cleansing wound dressings and injuries. It plays a crucial role in cleanliness maintenance and facilitating healing, essential for both everyday individuals and healthcare professionals.

INFORMATION FOR HEALTHCARE PROFESSIONAL AND LAY PERSON

Information	Healthcare Professional	Lay Person
Brand Name	RITE-FLUSH	RITE-FLUSH-L
Intended User	Intended to be used by only Healthcare Professional	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

Isotonic Saline Solution 0.9% w/v is sterile and nonpyrogenic isotonic solution which is indicated for general irrigation, washing body cavities, tissue or wounds, sterile irrigation of indwelling urethral catheter and surgical tubes.

INDICATION

HEALTHCARE PROFESSIONAL

- Washing, flushing or rinsing body cavities, tissues or wounds
- Irrigation of indwelling urethral catheter and surgical drainage tubes.
- Intra and postoperative bladder irrigation in urological surgical procedure, irrigation of the gastrointestinal tract, irrigation of fistulas and drainage, cleaning of wound dressing and injuries through direct contact or impregnated in wound dressing such as gauze pads and dressings.

LAY PERSON

- Washing, flushing or rinsing body cavities, tissues or wounds.
- Cleaning of wound dressing and injuries through direct contact or impregnated in wound dressing such as gauze pads and dressing

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

Isotonic Saline 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 area 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

Isotonic Saline Solution 0.9% w/v contains water and sodium chloride, which creates a gentle and effective solution for irrigating and cleaning body cavities, tissue and wounds. 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. Isotonic Saline solution 0.9% w/v is used for general irrigation, washing body cavities, tissues or wounds, or sterile irrigation of indwelling urethral catheters and surgical tubes, the solution helps to clean the affected area by removing debris, bacteria, and other contaminants.

CONTRAINDICATION

- Patients with congestive heart failure or hypertension should use this solution with caution, as excessive sodium intake can worsen their condition.
- Isotonic Saline solution 0.9% w/v should not be used during electrosurgical procedures
- Isotonic Saline solution 0.9% w/v 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.
- Isotonic Saline Solution 0.9% w/v 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

- Hold gently, twist off top
- 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 away from sunlight
- For single use only

INSTRUCTIONS FOR USE FOR HEALTHCARE PROFESSIONAL

- Ensure hands are clean before handling the solution.
- After opening, the solution must be used immediately.
- 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 or 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.
- Product should be stored at temperature between 2- 32°C and keep away from sunlight.
- 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 Isotonic Saline solution 0.9% w/v if the packaging is torn or shows signs of tampering.
- Do not use unless the solution is clear and the seal is intact.
- 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 Isotonic Saline solution 0.9% w/v on pregnant and breastfeeding 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

- FOR IRRIGATION ONLY, NOT FOR INJECTION.
- Do not warm above 150°F (66°C).
- Caution: contents are sterile in the unopened, undamaged package.
- 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.
- Do not resterilize.

SIDE EFFECTS

- Epistaxis
- Otalgia
- Pain
- Eye Burning
- 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

- Isotonic Saline Solution 0.9% w/v it is not effective against certain types of bacteria that can cause infections
- Potential for irritation: While Isotonic Saline Solution 0.9% w/v 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

Isotonic Saline solution 0.9% w/v 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

- Isotonic Saline Solution 0.9% w/v cleanse and irrigate the intended area, removing debris, contaminants, and pathogens without causing harm.
- It can be used to rinse medical equipment such as catheters, drainage tubes, and dressings, to remove debris and other contaminants.

CLINICAL SAFETY

- Isotonic Saline Solution 0.9% w/v is isotonic with the body fluids, which means it has the same concentration of solutes as the body fluids and does not cause any osmotic imbalances or damage to the surrounding tissues.
- Isotonic Solution Saline 0.9% w/v is non-toxic and safe for use on various tissue
- Isotonic Saline Solution 0.9% w/v is non-irritating to the tissues, which means it does not cause any local irritation or inflammation.
- Isotonic Saline Solution 0.9% w/v is sterile, which reduces the risk of infection or contamination when used for irrigation of indwelling urethral catheters and surgical drainage tubes.

KNOWN CHARACTERISTICS OF DEVICE IN CASE OF RE-USE

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

STERILIZATION

Isotonic Solution Saline 0.9% w/v 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); Steam 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 Isotonic Saline Solution 0.9% w/v leads to reversible side effects like infection/trouble/breathing/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.
- Protect from light. Do not re-sterilize.
- 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		LEGENCY 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 LEGENCY 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) Alsstr. 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.