

SODIUM CHLORIDE IRRIGATION & INHALATION SOLUTION 0.9% w/v

PACK INSERT

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PRODUCT NAME

Sodium Chloride Irrigation & Inhalation solution 0.9% w/v

COMPOSITION

Each ampoule contains:

Sodium Chloride Ph. Eur.....0.9% w/v

Water for Injection.....q.s.

INTENDED PURPOSE

Sodium Chloride Irrigation & Inhalation solution 0.9% w/v is used in respiratory therapy or for tracheal or lavage. This sterile, single-use device is intended to be used as an accessory to medicinal nonventilatory nebulizers for respiratory therapy or for tracheal inhalation or lavage therapy. Sodium Chloride Irrigation & Inhalation solution 0.9% w/v is used to wash, flush, or rinse parts of the body (e.g., wounds) or medical supplies/equipment (e.g., dressings, catheters, drainage tubes). This product must not be used for injection or during electrosurgical procedures.

INFORMATION FOR HEALTHCARE PROFESSIONAL AND LAY PERSON

Information	Healthcare Professional	Lay Person
Brand Name	L-POD	LM-POD
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

Sodium Chloride Irrigation & Inhalation solution 0.9% w/v is a sterile, non-pyrogenic, isotonic solution of sodium chloride in water for injection. It is typically used for inhalation therapy as well as irrigation of wounds, body cavities, and tissues. The solution is intended for single use only and should be discarded after use. The solution is also used in various medical procedures, including bronchoscopy, tracheotomy, and catheterization, where it is used to flush and clean the affected area. It is generally considered safe and well-tolerated, although it may cause adverse effects in rare cases, such as allergic reactions or electrolyte imbalances.

INDICATION

FOR HEALTHCARE PROFESSIONAL

- Respiratory Therapy
- Tracheal inhalation or lavage therapy
- This sterile, non-pyrogenic electrolyte solution is indicated for all general irrigation, washing, rinsing

FOR LAY PERSON

- Respiratory Therapy
- Tracheal inhalation or lavage therapy
- This sterile, non-pyrogenic electrolyte solution is indicated for all general irrigation, washing, rinsing
- Accessory to medicinal nonventilatory nebulizers for respiratory therapy according to doctor's order

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

Sodium Chloride Inhalation and irrigation Solution 0.9% w/v is for long term (intended for continuous use for more than 30 days)

USAGE FREQUENCY

Single use only

DOSAGE

2.5 ml to 5 ml up to 4 times a day as required.

INTENDED PATIENT POPULATION

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

PHYSICAL DATA

Physical state – Liquid

Appearance: Clear, colourless liquid

Odour: Odourless

Sterility – Sterile, pyrogen free

OPERATING PRINCIPLE

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. Sodium Chloride Irrigation & Inhalation solution 0.9% w/v with other medication by diluting inhaled through a nebulizer and pass into respiratory system and to produce sputum (mucus, or phlegm) from the mouth to help improve lung function in people with cystic fibrosis, or to collect sputum for medical testing. Sodium Chloride Irrigation & Inhalation solution 0.9% w/v intended to be used as an accessory to medicinal nonventilatory nebulizers for respiratory therapy or for tracheal inhalation or lavage therapy. Sodium Chloride Irrigation & Inhalation solution 0.9% w/v is based on its ability to provide a gentle and effective means of cleansing and irrigating body tissues and medical equipment. When used for irrigation, the solution helps to remove debris and bacteria from wounds, while also providing a moist environment that can promote healing. In medical settings, Sodium Chloride Irrigation & Inhalation solution 0.9% w/v is commonly used to rinse and flush medical equipment such as catheters, drainage tubes, and surgical instruments. It is also used to clean wounds, flush out nasal passages, and for all general irrigation, washing and rinsing.

CONTRAINDICATION

- Pregnancy and breastfeeding: There is limited information about the safety of sodium chloride solution during pregnancy and breastfeeding. Therefore, it is recommended to consult a healthcare provider before using it.
- Sodium Chloride Irrigation & Inhalation solution 0.9% w/v should not be used for irrigation during electrosurgical procedures.
- Sodium Chloride Irrigation & Inhalation solution 0.9% w/v should not be used in patients with active respiratory tract infections.

METHOD OF ADMINISTRATION

For Respiratory Inhalation, use the device with nebulizer; jet nebulizer; ultrasonic nebulizer or membrane nebulizer. Follow the instructions for use of the nebulizer you are using.

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.
- Follow the instructions to prepare the solution correctly.
- Use the solution as directed for irrigation or inhalation.
- Once the product's seal is opened, do not store any unused solution. Discard it immediately
- Used/empty ampoule should be safely disposed.
- If you have any concerns or questions, consult a healthcare professional.
- Thoroughly wash the wound with the contents of the ampoule, avoiding touching the wound.
- Use as per the manual of nebulizer or inhalation device suitable for the administration of the solution.
- Product should be stored at temperature between 2- 32°C and keep away from sunlight.
- Transfer the solution from the ampoule into the nebulizer chamber according to the device instructions.
- Seek professional medical attention for all serious wounds injuries.

INSTRUCTIONS FOR USE FOR HEALTHCARE PROFESSIONAL

- Administer the solution using appropriate medical devices for irrigation or inhalation.
- Monitor the patient for any adverse reactions during and after administration.
- Document the administration process and any patient responses.
- Store the solution as per manufacturer recommendations.
- Assess the patient's suitability for nebulizer therapy based on their medical condition and treatment plan.
- Review the prescribed medication and dosage regimen, as well as the patient's ability to use the nebulizer effectively.
- Use the irrigation solution to cleanse the wound or surgical site thoroughly.
- Ensure aseptic technique is maintained throughout the procedure to prevent contamination.



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.
- It may have no effect at all or an entirely unexpected effect if you use it after the expiry date.
- Do not use Sodium Chloride Irrigation & Inhalation 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.
- Tell your doctor if you have any allergies to:
 - Any other medicine.
 - 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 Sodium Chloride Irrigation & Inhalation Solution 0.9% w/v on pregnant and breastfeeding women. Hence, we do not recommend to use at this moment.
- Before Sodium Chloride Irrigation & Inhalation Solution 0.9% w/v is used, tell your doctor about any of these things and anything else which you feel is important.
- Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop. Some medicines may affect the way sodium chloride works. Your doctor will advise you about continuing to take other medicines.

WARNINGS

- FOR INHALATION & IRRIGATION PURPOSE ONLY, NOT FOR INJECTION
 - This device is not for parenteral use or for preparations intended for parenteral use.
 - Caution: Contents are sterile in the unopened, undamaged package.
 - 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 solution since it contains no preservatives.
 - Do not resterilize.
- SIDE EFFECTS**
- Epistaxis
 - Otalgia
 - Pain during inhalation
 - Pressure in Sino nasal
 - Discomfort
 - Trouble breathing
 - Nausea
 - Vomiting
 - Infection

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), trouble breathing, swelling, unusual weakness any infection, mental/mood changes (e.g., restlessness, irritability). This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

ADVERSE REACTIONS

- Overdose
 - Immediately telephone your doctor or go to your nearest hospital emergency department if you think that someone may have drunk Sodium Chloride Irrigation & Inhalation Solution 0.9% w/v even if there are no signs of discomfort or poisoning. Symptoms of overdose may include: trouble breathing, swelling of the arms/legs.

LIMITATIONS

- Sodium Chloride Irrigation & Inhalation solution 0.9% w/v may not be appropriate for patients with heart failure or renal impairment. It shall be used only after consulting the doctor.
- This device is not intended for parenteral use or for preparations intended for parenteral use.

CLINICAL BENEFITS

Inhalation of Sodium Chloride Inhalation solution 0.9% w/v hydrates the airways, improve airways clearance and reduce the symptoms associated with the cold or sinus infection, irrigation of solution helps to remove the foreign bodies and helps to prevent the infection

CLINICAL SAFETY

Sodium Chloride Irrigation & Inhalation solution 0.9% w/v safe for use on various tissues and surfaces, minimizing the risk of damage to tissue.

CLINICAL PERFORMANCE

- Sodium Chloride Irrigation & Inhalation solution 0.9% w/v effectively 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.

KNOWN CHARACTERISTICS OF DEVICE IN CASE OF RE-USE

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

STERILIZATION

Sodium Chloride Irrigation & Inhalation solution 0.9% w/v supplied in sterile condition

STERILIZATION TYPE

Aseptic Processing Technique

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 irrigation & inhalation of solution leads to reversible side effects like infection/trouble breathing/swelling/restlessness/irritability/unusual weakness

STORAGE & TRANSPORTATION

- Exposure of products to heat should be minimized.
- Avoid excessive heat.
- It is recommended that the product should be stored between 2- 32°C.
- Do not warm above 150°F (66°C).
- Keep away from sunlight.
- Keep dry.
- Do not resterilize.
- Discard unused portion.

HOW IS IT SUPPLIED

Device is packed in LDPE ampoules

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

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.	LOT	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	STERILE A	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.	REF	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 0297	CE mark with the Notified Body number
Unique Device Identifier	UDI	Indicates a carrier that contains Unique Device Identifier information
Instructions for Use		This symbol indicates that the accompanying documents must be consulted
Medical Device	MD	Indicates the item is a medical device
Authorized representative in the European Community / European Union	EC REP	EUROPECERT UG (HAFTUNGSBESCHRÄNKT) Alisstr., 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.