SODIUM CHLORIDE INHALATION SOLUTION 0.9% w/v
PACK INSERT

Doc No: LR-MDR-II-PI-01B **Rev No.: 00** **Date: 01.05.2024**

PRODUCT NAME
Sodium Chloride 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 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.

INFORMATION FOR HEALTHCARE PROFESSIONAL AND LAY PERSON

Information	Healthcare Professional	Lay Person
Brand Name	**LEENEB**	**LM-SALINE**
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 Inhalation solution 0.9% w/v is a sterile, non-pyrogenic, isotonic solution of sodium chloride in water for injection that is used for respiratory therapy. Sodium Chloride Inhalation Solution 0.9% w/v is also used to dilute medications for nebulization. It is important to note that this solution is for inhalation use only and should not be injected or used for any other purpose.

INDICATION

FOR HEALTHCARE PROFESSIONAL
- Respiratory Therapy
- Tracheal inhalation or lavage therapy

FOR LAY PERSON
- Respiratory Therapy
- Tracheal inhalation or lavage therapy
- 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 Solution 0.9% w/v is for long term (intended for continuous use for more than 30days)

USAGE FREQUENCY
Single use only

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

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 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. It is a sterile solution containing sodium chloride (NaCl) in water that is intended to be used for respiratory therapy, tracheal inhalation, or lavage therapy. The solution is delivered via a medicinal nonventilatory nebulizer, which is a device that turns liquid medication into a fine mist that can be inhaled into the lungs.
During respiratory therapy, the nebulizer is filled with the Sodium Chloride Inhalation Solution and attached to a compressor that delivers a controlled flow of air or oxygen to the nebulizer. The nebulizer then converts the solution into a mist that is inhaled through a mouthpiece or mask. This mist helps to moisten the respiratory tract, making it easier to breathe, and can also help to loosen mucus, making it easier to cough up.
In tracheal inhalation or lavage therapy, the solution is instilled directly into the trachea or lungs using a catheter or other specialized device. This can help to remove mucus, pus, or other substances from the respiratory tract, or to deliver medication directly to the site of infection or inflammation.

CONTRAINDICATION
- Patients with congestive heart failure or hypertension should use this solution with caution, as excessive sodium intake can worsen their condition.
- Sodium Chloride solution 0.9% w/v should not be used in patients with active respiratory tract infections.
- 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.

METHOD OF ADMINISTRATION
Inhalation 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
- Hold gently, twist off top
- Ensure hands are clean before handling the solution
- Follow the instructions to prepare the solution correctly
- Use the solution as directed for 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
- Pour the solution info the nebulizer. Follow the instruction for use of the nebulizer you are using
- Product should be stored at temperature between 2- 32°C and keep way from sunlight
- Transfer the solution from the ampoule into the nebulizer chamber according to the device instructions
- Unused portion of the solution should be discarded
- For single use only

INSTRUCTIONS FOR USE FOR HEALTHCARE PROFESSIONAL
- 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.

PRECAUTION
- Do not administer unless solution is clear, seal is intact, packaging and container is undamaged.
- 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 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 Inhalation Solution 0.9% w/v on pregnant and breast-feeding women. Hence, we do not recommend to use at this moment.
- Before Sodium Chloride 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 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 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 Inhalation solution 0.9% w/v may not be appropriate for patients with heart failure or renal impairment. It shall b 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 0.9% w/v Sodium Chloride Inhalation solution hydrates the airways, improves airways clearance and reduce the symptoms associated with the cold or sinus infection.

CLINICAL PERFORMANCE
- Sodium Chloride Inhalation solution 0.9% w/v, is used to moisturize and lubricate the respiratory tract. It helps in thinning mucus secretions, making it easier to clear them from the airways.
- Sodium Chloride Inhalation solution 0.9% w/v therapy can improve airway clearance by hydrating the airway surfaces, thereby promoting effective coughing and clearance of mucus. This can help to improve respiratory function.
- Sodium Chloride Inhalation solution 0.9% w/v is compatible with medicinal nebulizers and can be used with a variety of medications such as bronchodilators, corticosteroids and mucolytics. It can enhance the effectiveness of these medications by optimizing airway hydration and clearance.

CLINICAL SAFETY
- Sodium Chloride Inhalation solution 0.9% w/v well-tolerated by the body when used for inhalation therapy.
- Sodium Chloride Inhalation solution 0.9% w/v used for inhalation therapy is not known to interact with medications commonly prescribed for respiratory conditions. It can be safely used as adjunctive therapy alongside other respiratory medications, such as bronchodilators or corticosteroids.

KNOWN CHARACTERISTICS OF DEVICE IN CASE OF RE-USE
- Any infectious disease can transfer
- Chances of Cross-contamination

STERILIZATION
Sodium Chloride 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 Sodium Chloride Inhalation solution 0.9% w/v 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 TO 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:** legency.remedies@rediffmail.com **Website:** www.legencyremedies.com
Manufacturer	IN	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)** 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.