

PHYSIOLOGICAL SALINE SOLUTION 0.9% w/v PACK INSERT

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PRODUCT NAME

Physiological Saline Solution 0.9% w/v

COMPOSITION

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

INTENDED PURPOSE

Physiological Saline Solution 0.9% w/v is intended to clean excess mucus from the nose or clean the ears by compressing the bottle. It can also be used by pouring a few drops directly into the eyes, ears, or nose. Suitable for single-use, it can be applied daily to clean the noses of babies, children, and adults. Additionally, it acts as an accessory to non-ventilatory nebulizers for respiratory therapy under the orders of healthcare professionals. It is also designed for washing, flushing, or rinsing medical supplies and equipment, such as dressings, nasal aspirators, and instruments. Furthermore, it can be used to wash, flush, or rinse parts of the body, including wounds and allergy particles.

INFORMATION FOR HEALTHCARE PROFESSIONAL AND LAY PERSON

Information	Healthcare Professional	Lay Person
Brand Name	LEEPAK	LM-PACK
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

Physiological saline solution 0.9% w/v is a sterile, isotonic solution that contains 0.9% (w/v) of sodium chloride (NaCl) dissolved in water which is indicated to clean excess mucus from the nose or to clean the ears with a compression of bottle or by pouring a few drops directly in the eyes or ears. It is also used to clean the noses of babies, children's and adult's noses on a daily basis.

INDICATION:

- Cleaning excess mucus from the nose.
- Clogging of nose due to excessive mucus.
- Cleaning of eye, nose and ear.
- Accessory to medicinal nonventilatory nebulizers for respiratory therapy.
- Washing and irrigation of wound.

FOR LAY PERSON

- Cleaning excess mucus from the nose
- Clogging of nose due to excessive mucus
- Accessory to medicinal nonventilatory nebulizers for respiratory therapy according to doctor's order
- Washing and irrigation of wound
- Cleaning of eye, nose and ear

INTENDED PATIENT POPULATION

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

SHelf LIFE OF DEVICE

5 years from date of manufacturing use

DURATION OF USE

Physiological saline solution is for long term 0.9% w/v (Adults, Babies Ear, Nose, Eyes and Inhalation) (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 for inhalation or as required for irrigation depends on the clinical condition.

PHYSICAL DATA

Physical state - Liquid

Appearance: Clear, colourless liquid

Odour: Odourless

Sterility - Sterile, pyrogen free

OPERATING PRINCIPLE

Physiological saline solution 0.9% w/v, also known as normal saline, is a sterile solution of sodium chloride (NaCl) in water. It is often used as a respiratory treatment to help moisten and loosen mucus in the airways, making it easier to breathe. 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. Physiological saline solution 0.9% w/v has the same osmotic pressure as the body's fluids, making it isotonic. This means that it has the same concentration of salt as the body's cells and fluids, which allows it to be safely used in the body without causing damage to cells or tissues. The salt in the solution has a mild antibacterial effect, which can help to reduce the risk of respiratory infections. It also has a soothing effect on irritated respiratory tissues.

CONTRAINDICATION

- Patients with congestive heart failure or hypertension should use this solution with caution, as excessive sodium intake can worsen their condition.
- Physiological saline solution should not be used in patients with active respiratory tract infections
- Physiological saline solution 0.9% w/v should not be used in patients and especially babies having an eye infection, such as conjunctivitis, using the solution to clean the eyes, could aggravate the infection and lead to further complications.
- Physiological saline solution 0.9% w/v should not be used if there is any trauma or injury to the nose or eyes, until the injury has healed.
- Physiological saline solution 0.9% w/v should not be used if a person has recently had surgery in the nose or eyes, until the surgeon approves it.
- Pregnancy and breastfeeding: There is limited information about the safety of Physiological Saline Solution 0.9% w/v during pregnancy and breastfeeding. Therefore, it is recommended to consult a healthcare provider before using it.

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

- Hold gently, twist off top
- Ensure hands are clean before handling the solution.
- 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.
- Pour the solution into the nebulizer. Follow the instruction for use of the nebulizer you are using
- Thoroughly wash the wound with the contents of the ampoule, avoiding touching the wound.
- If you are using the solution for eye or ear cleaning, place few drops in eye or ear and Wipe off excess with the compress. Repeat the procedure for other eye or ear OR Soak a cotton ball with the saline solution and gently clean eyes and ear.
- Taking care not to bring the ampoule into contact with eye, ear or with nose surface while 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.
- For single use only



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 using the product.
- 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 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 Physiological 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.

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 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 Physiological Saline solution 0.9% w/v on pregnant and breast-feeding women. Hence, we do not recommend to use at this moment.
- Before Physiological Saline 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
- Keep out of reach of children

WARNINGS

- 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
- Discard unused portion

SIDE EFFECTS

- Epistaxis
- Otalgia
- Pain during inhalation
- Pressure in Sino nasal
- Discomfort
- Trouble breathing
- Nausea
- Vomiting
- Infection.
- Physiological Saline solution 0.9% w/v may have some unwanted side effects in a few people. If they occur, most are likely to be minor or temporary. However, seek immediate medical attention if you notice any of the following symptoms of a

serious allergic reaction: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. 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 Physiological Saline 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

- Physiological Saline 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

Physiological Saline Solution 0.9% w/v enhances patient care by hydrating the airways, improving airway clearance, and reducing symptoms associated with colds or sinus infections. It effectively cleans and moisturizes the nasal passages, eyes, and ears; it aids respiratory therapy with nebulizers, helps remove debris and foreign materials from the eyes, wounds, and medical equipment, and maintains cleanliness of medical supplies and instruments.

CLINICAL SAFETY

- Physiological Saline Solution 0.9% w/v is safe for use on various tissues and surfaces, minimizing the risk of damage to tissue.
- Physiological Saline Solution 0.9% w/v well-tolerated by the body when used for inhalation therapy.

- Physiological Saline 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.

CLINICAL PERFORMANCE

- Physiological saline solution 0.9% w/v helps to improve the clearance of mucus in the respiratory tract, making it easier to breathe.
- Physiological saline solution 0.9% w/v effectively cleanse and irrigate the intended area, removing debris, contaminants, and pathogens without causing harm.
- Physiological Saline Solution 0.9% w/v is compatible with medicinal nebulizers and can be used with a variety of medications such as bronchodilators, corticosteroids.

KNOWN CHARACTERISTICS OF DEVICE IN CASE OF RE-USE

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

STERILIZATION

Physiological saline 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 Physiological Saline 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.
- Do not re-sterilize.
- 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 resterilized.
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. Kt 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 (HAFTUNGSBESCHRÄNKTE) Alsstr. 97 41063 Monchengladbach, Germany. Tel. +49 21619908831 Email: support@europcert.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		