1.6 Product Information

1.6.1 Prescribing Information (Summary of Product Characteristics)

1. Name of the finished Pharmaceutical Product:

AXALINE-N (Sodium Chloride 0.9%w/v Nasal Drops)

1.1 Strength

0.9%w/v

1.2 Pharmaceutical form

Nasal drops

2. Qualitative and Quantitative Composition:

2.1 Qualitative declaration

Product Name: AXALINE-N

Generic Name: Sodium Chloride 0.9%w/v Nasal Drops

Label Claim: Each mL contains:

Sodium Chloride BP…….…….....0.9%w/v
Benzalkonium Chloride Solution BP…...0.02%v/v
(As preservative)
Aqueous Buffered vehicle.……..…….q.s

2.2 Quantitative declaration

S. No.	Name of Ingredient	Reference	Qty./10mL	Function of Ingredient
1.	*Sodium Chloride	BP	90.000mg	Active Ingredient
2.	*Benzalkonium Chloride Solution	BP	0.00002mL	Preservative
3.	Sodium Hydroxide	BP	2.181mg	pH adjustment
4.	Water for Injections	BP	q.s per 10 mL	vehicle

* These materials are to be dispensed on 100% assay Value.

2.3 Salts and hydrates

NA

3. Pharmaceutical Form

Nasal Drops

4. Clinical Particulars

4.1 Therapeutic indications

It is indicated to treat dry or irritated nose passages. It is used to thin fluid in the nose passages

Post-nasal surgery

4.2 Posology and method of administration

Sodium chloride 0.9%w/v relieves nasal congestion by thinning mucus and moisturizes membranes

Children over 2 years and adults: 1 to 2 drops into each nostril as required

Infants and babies up to 2 years : 1 drops into each as required

4.3 Contraindications

Hypersensitivity to preservatives or buffers

4.4 Special warnings and precautions for use

Signs of an allergic reaction, Like rash : hives: itching: red, red, swollen, blistered, or peeling skin with or without fever: wheezing; tightness in the chest or throat: trouble breathing, swallowing, or taking unusual hoarseness or swelling of the mouth, face, lips, tongue or throat.

Very bad nose irritation

4.5 Interaction with other medicinal product and other forms of interaction

There are no drug interactions listed for this product.

4.6 Pregnancy and Lactation

Pregnancy Category: A

Generally acceptable. Controlled studies in pregnant women show no evidence of fetal risk,

Lactation: Not distributed in breast milk

4.7 Effects on ability to drive and use machines

No information Provided

4.8 Undesirable effects

Intranasal Sodium Chloride rarely causes side effects of this product may include:

Allergic reaction (rare)

Sneezing

Cough

Nose irritation

Abnormal taste

4.9 Overdose

No information Provided

5. Pharmacological properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Other nasal preparation

ATC Code: R01AX10

Provides Moisture to dry or inhaled mucus membranes, and helps thin mucous. Intranasal sodium chloride solution is a purified salt solution used for wetting the nasal passages.

5.2 Pharmacokinetic Properties

It moisturizes the nose and helps dissolve and loosen thick mucus most often associated with the common cold. Intranasal sodium Chloride does not contain any active medication

5.3 Preclinical safety data

No information Provided

6.0 Pharmaceutical particulars

6.1 List of Excipients

Sodium chloride, Benzalkonium chloride solution, Sodium hydroxide, Water for injections

6.2 Incompatibilities

None known.

6.3 Shelf life

24 months from the date of manufacturing.

6.4 Special precautions for storage

Store below 30ºC. Protect from light. Do not refrigerate or freeze.

6.5 Nature and contents of container

10 ml LDPE vial

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Tighten the cap on the nozzle as shown.
The spike in the cap will pierce the tip of the vial.
Dispense drops with gentle pressure.
Replace the cap after every use.
Not for Injection. For External Use Only
Use the solution within one month after opening the vial.

7. Marketing Authorization Holder

Axa Parenterals Limited
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E-Mail: axapar@axapar.com

8. Marketing Authorization Number(s)

NA

9. Date of first authorization/renewal of the authorization

NA

10. Date of revision of the text

NA