Prescribing Information (Summary of Product Characteristics)

"Prescription only medicine"

1. Name of the Medicinal Product:

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

2. Qualitative and Quantitative Composition:

a) Qualitative Composition

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

b) Quantitative Composition

One mL contains: 9 mg Sodium Chloride BP
One 10mL vial contains: 90 mg Sodium Chloride BP
Excipients with known effects:
Benzalkonium Chloride Solution BP: 0.002 mL/vial
For a full list of excipients, see section 6.1.

Average Fill Volume: 10 mL

For the full list of excipients, see section 6.1.

3. Pharmaceutical Form

Nasal Drops
Description: Clear colourless solution

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.

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.

This product contains Benzalkonium chloride Solution which may cause irritation or swelling inside the nose, especially if used for a long time. Long term use may cause oedema of the nasal mucosa.

4.5 Interaction with other medicinal product and other forms of interaction

There are no drug interactions listed for this product.

4.6 Fertility, 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 studies on the effects on the ability to drive and use machines have been performed.

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
None

5. Pharmacological properties
5.1 Pharmacodynamic Properties
Pharmacotherapeutic group: Other nasal preparations, ATC Code: R01AX10
Provide moisture to dry or inflamed mucus. Intranasal sodium chloride is a purified salt solution is a purified salt solution used for wetting the nasal passages.

5.2 Pharmacokinetic Properties
Sodium chloride distributes primarily to extracellular compartments, including plasma and interstitial fluid; sodium is maintained outside the cell via the Na+/K+-ATPase pump, which exchanges intracellular sodium for extracellular potassium. Penetration across the blood-brain barrier is low. Sodium chloride is excreted primarily in the urine, but it is also excreted in sweat and stool. In healthy patients at steady state with minimal sweat losses, sodium excreted in urine is roughly the same as dietary intake.
Sweat sodium concentration is increased in children with cystic fibrosis, aldosterone deficiency, or pseudohypoaldosteronism.

5.3 Preclinical safety data
No information provided

6.0 Pharmaceutical particulars
6.1 List of Excipients
Benzalkonium Chloride Solution BP, Sodium Hydroxide BP, Water for Injections BP.

6.2 Incompatibilities
None known

6.3 Shelf life
24 months from the date of manufacturing. Use the solution within one month after opening the vial.

6.4 Special precautions for storage
Do not store above 30ºC. Protect from light. Do not refrigerate or freeze.

6.5 Nature and contents of container
1x10 mL LDPE vial packed in unit carton along with pack insert.

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.
Keep out of reach of children.
Shake well before use.

7. Marketing Authorization Holder
Axa Parenterals Limited,
Plot No.: 936, 937 & 939
Vill. Kishanpur, Jamalpur, Roorkee-247667
Distt. Haridwar (Uttarakhand), **India.**
Telephone: +91-1332-234041/42/43
Telefax: +91-1332-234040
E-mail: dra@axapar.com

8. Marketing Authorization Number(s)
TAN 22 HM 0116

9. Date of first authorization/renewal of the authorization
11/04/2022

10. Date of revision of the text