# Summary of Product Characteristics

## 1. Name of the medicinal product

SODIUM CHLORIDE 0.9% w/v NASAL DROPS**(ABNAL)**

## 2. Qualitative and quantitative composition

Each ml contains 0.9% w/v Sodium Chloride B.P

Excipient(s) with known effect: Benzalkonium Chloride

For full list of excipients, see section 6.1.

## 3. Pharmaceutical form

Nasal drops, Solution

Clear, colourlesssolution.

## 4. Clinical particulars

### 4.1 Therapeutic indications

For relieving nasal congestion by dissolving and softening thick and crusty mucus in the nose.

### 4.2 Posology and method of administration

Posology

Saline solution is recommended for children and adults.

Apply one or two drops in each nostril as needed or directed by the physician.

Method of administration

Turn your head to the left in the extended position. Gently introduce the tip at the entrance of the right nostril. Press the vial. Turn the head on the other side and repeat the same operation with the other nostril.

### 4.3 Contraindications

There are no absolute contraindications to use ABNAL.

### 4.4 Special warnings and special precautions for use

Before use, tell the doctor or pharmacist if you are allergic to any of the ingredients.

Signs of an allergic reaction may include: rash, hives, itching, red-swollen-blistered or peeling skin with or without fever, wheezing, tightness in the chest or throat, trouble breathing, swallowing, unusual hoarseness or swelling of the mouth, face, lips, tongue or throat. Very bad nose irritation.

The 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.

Before use, ensure that the container is undamaged and the contents clear in appearance. After use, discard any remaining solution.

**4.5 Interaction with other medicinal products and other forms of interaction**

None

**4.6 Fertility, pregnancy and lactation**

Safe to use during pregnancy and lactation.

**4.7 Effects on ability to drive and use machines**

None known

**4.8 Undesirable effects**

Usually do not occur, however rarely occurring side effects may include:

-if the inside of the nose is very dry and irritated, stinging may occur.

-allergic reactions

-sneezing

-cough

-nose irritation

-abnormal taste

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions.

**4.9 Overdose**

None

## 5. Pharmacological Properties

**5.1 Pharmacodynamic properties**

**Pharmacotherapeutic group**: Decongestants and other nasal preparations, sodium chloride nasal drops

**ATC code**: R01AX10

The exact mechanism of action of saline nasal irrigation is unknown. One possibility is that the breakdown of the protective function of the nasal mucosa plays a role in upper respiratory conditions. Saline nasal irrigation may improve nasal mucosa function through several

physiologic effects, including direct cleansing, removal of inflammatory mediators and improved mucociliary function, as suggested by increasing ciliary beat frequency.

### 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 further information other than that which is included in the Summary of Product Characteristics.

## 6. Pharmaceutical particulars

### 6.1 List of excipients

- Benzalkonium chloride
- Water for injection

### 6.2 Incompatibilities

None known

### 6.3 Shelf life

Unopened: 36 months.

Use within 28 days of first opening

Discard four weeks of first opening

### 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

10mL or 5mL Low density polyethylene (LDPE) dropper bottles with a white screw cap in pack sizes of 10mL and 5mL.

### 6.6 Special precautions for disposal and other handling

Use as directed by physician. Keep out of reach of children.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

**7. Marketing authorization holder**

Abacus Parenteral Drugs Limited
Block 191, Plot no.114, Kinga Mukono
P.O.BOX, 31376, Kampala, Uganda.
Email:apdl@abacuspharma.com
Website: www.abacusparenteral.com

**8. Marketing authorization number(s)**

N/A

**9. Date of first authorization/renewal of the authorization**

Dec 2019

**10. Date of revision of the text**

July 2023