Summary of Product Characteristics
TASALINE 3%
(Sodium Chloride 3% w/v Solution for Nebulisation)

1 Name of the medicinal product

Tasaline 3% – Sodium Chloride 3% Solution for Nebulisation

2 Qualitative and quantitative composition

Each 4 ml single-dose ampoule contains 120 mg sodium chloride (equivalent to 3% w/v; 30 mg sodium chloride per ml), corresponding to approximately 47 mg sodium per ampoule.

For the full list of excipients, see section 6.1.

3 Pharmaceutical form

Solution for nebulisation.

Appearance: clear, colourless solution.

4 Clinical particulars

4.1 Therapeutic indications

Tasaline 3% is a sterile hypertonic (3%) saline solution for inhalation, indicated for use in patients with respiratory conditions leading to retained bronchopulmonary secretions, where usual airway-clearance measures (physiotherapy/airway clearance techniques, adequate systemic hydration and mucolytic therapy where indicated) are not sufficiently effective. This includes:

- cystic fibrosis;
- bronchiectasis – for use prior to airway clearance to increase sputum yield, reduce sputum viscosity and ease expectoration;
- other conditions associated with persistent mucus production or sputum plugging, including complex chronic obstructive pulmonary disease (COPD) or asthma where standard treatments are ineffective.

Nebulised hypertonic saline may cause bronchoconstriction and a reduction in lung function, particularly in patients with COPD or bronchial hyper-reactivity; extra care should be taken in these patients (see section 4.4).

4.2 Posology and method of administration

Posology

The recommended dose is one single-dose ampoule (4 ml) inhaled undiluted via a nebuliser 2 to 4 times a day. The dose should be individualised according to the status of the patient and age group, and should be reassessed at regular intervals according to symptoms.

The suitability of the patient for treatment should be assessed using an initial test dose administered under medical supervision, with monitoring of lung

function (for example FEV1) and for signs of bronchospasm, particularly in patients who display a tendency to develop dyspnoea or bronchial hyper-reactivity. If the initial test dose is not tolerated, treatment should not be continued (see section 4.4).

Where the patient is also prescribed other airway therapies, the recommended sequence for airway clearance is: bronchodilator first (where prescribed), followed by the mucoactive treatment (hypertonic saline), then airway clearance, and finally any nebulised antibiotic and/or inhaled corticosteroid (see section 4.5).

Adults, older people and children

Tasaline 3% is to be used on its own and should not be taken orally. Each ampoule contains 4 ml of solution. Nebulised hypertonic saline is used in children with cystic fibrosis and other suppurative lung conditions; the dose and suitability of treatment should be determined by a physician experienced in the management of these conditions, with appropriate supervision at treatment initiation.

Method of administration

For inhalation use only. The solution is administered by inhalation from a suitable nebuliser or an intermittent positive-pressure ventilator, after the single-dose ampoule has been opened and its contents transferred to the nebuliser chamber. Administration should be in accordance with the device manufacturer's instructions. The solution must not be injected or swallowed.

Prepare the nebuliser by following the manufacturer's instructions and the advice of the physician:

- Carefully open a new ampoule. Never use an ampoule that has already been opened.
- Empty the contents of the ampoule into the nebuliser chamber, using a dosing syringe as required.
- Assemble the nebuliser and use it as directed.
- After nebulisation, clean the nebuliser according to the manufacturer's instructions; it is important that the nebuliser is kept clean.
- As the single-dose ampoules contain no preservative, the contents must be used immediately after opening and a fresh ampoule used for each administration to avoid microbial contamination.
- Partly used, opened or damaged single-dose ampoules should be discarded.
- Any solution remaining in the nebuliser chamber should be discarded.

4.3 Contraindications

- Hypersensitivity to the active substance (sodium chloride) or to any of the excipients listed in section 6.1.
- Active haemoptysis.

The solution must not be injected or administered orally.

4.4 Special warnings and precautions for use

Bronchospasm

Inhalation of hypertonic saline may cause bronchoconstriction, chest tightness, wheezing and cough. The first dose should be administered under medical supervision, with monitoring of lung function and for signs of bronchospasm. In patients with bronchial hyper-reactivity or asthma, pre-treatment with a bronchodilator should be considered. If bronchospasm or a significant fall in lung function occurs, treatment should be discontinued and appropriate management (including a bronchodilator) instituted. If the initial test dose is not tolerated, treatment should not be continued.

Chronic obstructive pulmonary disease

Evidence of therapeutic value in patients with COPD is limited compared with cystic fibrosis and bronchiectasis, and hypertonic saline may cause a reduction in lung function due to bronchoconstriction in these patients. Extra care should be taken and the benefit of treatment reassessed in patients with COPD.

General precautions

Do not use unless the solution is clear and the pack intact. Any surplus should be discarded after use. Tasaline 3% should be used with a nebuliser only under the direction of a physician. Patients using nebuliser solutions at home should be advised that, if the usual relief is diminished or the usual duration of action is reduced, they should consult their doctor. Tasaline 3% is for inhalation only; it should not be swallowed, injected or administered by any other route, and the ampoules are for single use only.

4.5 Interaction with other medicinal products and other forms of interaction

Tasaline 3% must not be mixed with any other nebulised medicinal products in the same nebuliser chamber. No interactions with systemically administered medicines are known.

Because hypertonic saline increases bronchopulmonary clearance, it should not be inhaled immediately after other inhaled medicines that are intended to remain in the airways to exert their effect (for example inhaled corticosteroids, nebulised antibiotics or dornase alfa). The recommended airway-clearance sequence is given in section 4.2.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no adequate data from the use of sodium chloride 3% in pregnant women. However, sodium chloride is a normal physiological constituent of the body, and the nebulised route results in negligible systemic exposure, so no effects on pregnancy are anticipated. Tasaline 3% may be used during pregnancy where clinically indicated, after the physician has carefully considered the potential risks and benefits for the individual patient.

Breast-feeding

No effects on the breast-fed newborn/infant are anticipated. Tasaline 3% may be used during breast-feeding where clinically indicated.

Fertility

No effects on fertility are anticipated.

4.7 Effects on ability to drive and use machines

Tasaline 3% has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Summary of the safety profile

The most commonly reported adverse reactions to nebulised hypertonic saline relate to local airway irritation and include cough, throat irritation and chest tightness. Hypertonic saline may also provoke reversible bronchoconstriction, particularly in patients with bronchial hyper-reactivity. These reactions are generally transient and reversible.

Tabulated list of adverse reactions

Adverse reactions are listed below by System Organ Class (MedDRA) and frequency. Frequencies are defined as: very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), very rare (< 1/10,000) and not known (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse reaction
Respiratory, thoracic and mediastinal disorders	Rare	Temporary irritation (e.g. cough) or reversible bronchoconstriction
	Not known	Throat (pharyngeal) irritation, hoarseness, chest tightness, wheezing, dyspnoea
Nervous system disorders	Not known	Dysgeusia (salty 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 to the National Regulatory Authority.

4.9 Overdose

Overdose by the nebulised route is unlikely to produce systemic effects, as sodium chloride is a normal physiological constituent handled by the body's usual homeostatic mechanisms. Excessive inhalation may increase local airway irritation (cough, throat irritation) and the risk of bronchospasm; treatment is symptomatic and supportive, including cessation of nebulisation and administration of a bronchodilator if bronchospasm occurs. Substantial oral ingestion may require the use of a diuretic to remove excess sodium and, with very large amounts, correction of any disturbance of sodium balance.

5 Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Solutions affecting the electrolyte balance; sodium chloride.

ATC code: B05XA03

Sodium chloride 3% solution for nebulisation is hypertonic, with an approximate osmolarity of 1027 mOsm/l.

Mechanism of action

When inhaled as a fine aerosol, hypertonic (3%) saline acts locally on the airway surface by drawing water into the airway surface liquid through its osmotic effect, thereby hydrating and humidifying the airways. This increases the volume and reduces the viscosity of bronchial secretions, restores the periciliary liquid layer, improves mucociliary clearance and facilitates the mobilisation and expectoration of retained secretions. The osmotic stimulus may also induce cough, which further assists clearance of secretions.

Pharmacodynamic effects

In patients with cystic fibrosis and bronchiectasis, regular nebulised hypertonic saline increases sputum yield, reduces sputum viscosity and can improve measures of lung function and quality of life when used as part of an airway-clearance regimen. The osmotic effect that produces these benefits can also provoke bronchoconstriction in susceptible patients (see sections 4.2 and 4.4).

5.2 Pharmacokinetic properties

Sodium chloride is a physiological electrolyte and no formal pharmacokinetic studies have been performed with nebulised hypertonic saline. The solution acts locally on the airway surface. Any sodium and chloride absorbed from the respiratory or gastrointestinal tract enters the body's normal electrolyte pools and is subject to the usual homeostatic regulation, principally renal excretion. Given the small quantities delivered by the nebulised route, systemic exposure is negligible.

5.3 Preclinical safety data

Sodium chloride is a normal physiological constituent of body fluids. There are no preclinical safety data of relevance to the prescriber beyond that already included in other sections of this Summary of Product Characteristics.

6 Pharmaceutical particulars

6.1 List of excipients

- Water for injections
- Hydrochloric acid (for pH adjustment)
- Sodium hydroxide (for pH adjustment)

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products. In particular, it must not be mixed with other nebulised medicines in the same nebuliser chamber.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Do not store above 30°C.

Keep out of the sight and reach of children.

6.5 Nature and contents of container

USP Type I clear glass ampoules, each containing 4 ml of solution, in packs of 5 or 10 ampoules (5 × 4 ml, 10 × 4 ml).

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

For nebulisation use only. For single use only. The ampoule should be opened immediately before use and the contents used immediately after opening; a fresh ampoule should be used for each administration. Do not use if the solution is cloudy or coloured, or if the container is damaged or leaking. Partly used, opened or damaged ampoules and any solution remaining after use should be discarded.

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

7 Marketing authorisation holder

Tasa Pharma Limited

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Nairobi

Kenya

Manufacturer

Tasa Pharma Limited

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8 Marketing authorisation number

9 Date of first authorisation/renewal of the authorisation

10 Date of revision of the text