PROFESSIONAL INFORMATION

LINCTAGON® SALINE NASAL SPRAY
- Complementary Medicine.
- D.5.8 Preparations for the common cold including nasal decongestants.
- This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS
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1. NAME OF THE MEDICINE
LINCTAGON® SALINE NASAL SPRAY

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 1 ml nasal spray contains:

Active ingredients	Per 1 ml nasal spray
Erythritol	100 mg
Sodium chloride	6,50 mg

Linctagon® Saline Nasal Spray contains sugar: Erythritol 100 mg/ml.
Linctagon® Saline Nasal Spray contains preservatives: Cetrimide 0,2 mg/ml.
For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Liquid.
Linctagon® Saline Nasal Spray is a clear solution.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
A hypertonic nasal spray for the temporary relief of nasal congestion due to colds, sinusitis, hay fever or allergies.
Linctagon® Saline Nasal Spray can act as a nasal irrigator and moisturiser.

4.2 Posology and method of administration
The recommended daily dosage is
Adults and children 12 years and older:
Two (2) sprays in each nostril, three (3) times per day or use as required to cleanse the nasal passages and sinuses.
Children between 2 – 12 years:
One (1) spray in each nostril, three (3) times per day or use as required to cleanse the nasal passages and sinuses.
Advise patients to clear the nasal passageway by gently blowing their nose before use.
Advise patients not to exceed the daily dose.
Advise patients to use within 30 days after opening.

4.3 Contraindications
- Must not be given to patients with known hypersensitivity to any of the ingredients of Linctagon® Saline Nasal Spray (see section 6.1 List of excipients). Patients should be advised to consult their medical practitioner if in doubt.
- Must not be given to patients with rare hereditary erythritol-intolerance.

4.4 Special warnings and precautions for use
- Linctagon® Saline Nasal Spray contains erythritol, which may have a laxative effect.
- Do not exceed the daily recommended dose.
- Do not use after the date of expiry.
- Use within 30 days of opening.

Porphyria
Safety has not been established.

4.5 Interaction with other medicinal products and other forms of interactions
No interaction studies have been performed on Linctagon® Saline Nasal Spray, see below interactions with individual ingredients.
No relevant interactions with other medications are anticipated when considering the small quantity of the dose and the method of administration.

4.6 Fertility, pregnancy and lactation
Pregnancy
Safety of some of the ingredients for use during pregnancy has not been established, therefore this product should not be used in patients who are pregnant.
Breastfeeding
Safety of some of the ingredients for use during lactation (breastfeeding) has not been established, therefore this product should not be used if patients are lactating (breastfeeding).
Fertility
There are no known effects of Linctagon® Saline Nasal Spray on fertility.

4.7 Effects on the ability to drive and use machines.
Based on the side effect profile, Linctagon® Saline Nasal Spray should not affect your ability to drive or operate machinery.

4.8 Undesirable effects
Linctagon® Saline Nasal Spray is generally well tolerated with the occurrence of adverse events unknown.
Patients experiencing any side effects or sensitivity to any of the ingredients, should discontinue use.
Adverse reactions reported in the literature are listed below, by system organ class 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).
- not known (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse Event
Respiratory, thoracic and	Frequency unknown	Burning or stinging of the nose, increased nasal
mediastinal disorders		discharge, sneezing, unpleasant smell and taste.

If symptoms persist, or if any adverse reactions occur, advise the patient to consult a healthcare provider.

Reporting of suspected adverse reactions
Reporting of suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**," found online under SAHPRA's publications: https://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf

4.9 Overdose
Symptoms
See **4.8 Undesirable effects**
In overdose, side effects can be precipitated and/or be increased.
There is no evidence that this product can lead to an overdose when used as recommended.
Treatment
If an accidental overdose occurs, treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Category and class: D.5.8 Preparations for the common cold including nasal decongestants.
Pharmacotherapeutic classification: Other nasal preparations.
ATC code: R01AX.

Erythritol
Erythritol, a tetritol polyol, is a sugar alcohol.
Erythritol has shown potential in inhibiting the growth of certain pathogenic bacteria strains.
Erythritol has no effect on blood sugar or blood insulin levels.
Sodium chloride
Nasal irrigation has been used traditionally to help facilitate drainage from the nose and sinuses, the process involves flushing out the nasal cavity with saline.
Research shows that nasal irrigation reduces symptoms of allergic rhinitis in both children and adults for up to 3 months. There is also some evidence that nasal irrigation reduces symptoms of various respiratory tract infections.

5.2 Pharmacokinetic properties
Erythritol
Absorption: Erythritol is absorbed rapidly into the blood, with peak amounts occurring in under two hours.
Excretion: The majority of an oral dose (80 to 90%) is excreted unchanged in the urine within 24 hours.
Sodium chloride
Absorption: Following oral intake of sodium chloride, the small intestines absorb approximately 98% of sodium.
Distribution: Absorbed sodium and sodium that has been filtered and reabsorbed by the kidneys is distributed to extracellular compartments.
Excretion: In patients with a sodium and fluid balance at "steady state", sodium excretion in the urine is equal to sodium intake.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Cetrimide.
Purified water.

6.2 Incompatibilities
None known.

6.3 Shelf life
24 months.

6.4 Special precautions for storage
- Store in a dry place at or below 25 °C.
- Protect from light and moisture.
- Do not use after the expiry date printed on the carton.

6.5 Nature and contents of container
Linctagon® Saline Nasal Spray is a clear solution.
Linctagon® Saline Nasal Spray is packed into a 20 ml amber glass bottle with a metered-dose nozzle and includes a patient information leaflet in a printed unit carton.

6.6 Special precautions for disposal and other handling
No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION
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8. REGISTRATION NUMBER(S)
To be allocated.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
To be allocated.

10. DATE OF REVISION OF THE TEXT
July 2022.

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