PROFESSIONAL INFORMATION
LINCTAGON® JUNIOR SALINE NASAL SPRAY

- Complementary Medicine
- Discipline: 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® JUNIOR SALINE NASAL SPRAY

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 1 ml syrup contains:

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

Linctagon® Junior Saline Nasal Spray contains a preservative: cetrimide 0,2 mg / ml.
Linctagon® Junior Saline Nasal Spray contains a sugar: erythritol 100 mg / ml.
For full list of excipients, see section 6.1.

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

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
Linctagon® Junior Saline Nasal Spray is a hypertonic nasal spray for the temporary relief of nasal congestion due to colds, sinusitis, hay fever or allergies.
Linctagon® Junior 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:
Spray two (2) sprays in each nostril three (3) times a day, or use as required to cleanse the nasal passages and sinuses.
Children between 2 -12 years:
Spray one (1) spray in each nostril three (3) times a day, or use as required to cleanse the nasal passages and sinuses.
Babies between 0 – 2 years:
Spray the mist in the air in front of the baby's nose.
Not to be sprayed directly into the nose at a young age.
Use within 30 days after opening.
4.3 Contraindications
- Hypersensitivity to the any of the active substances or any other ingredients in Linctagon® Junior Saline Nasal Spray (see 6.1 List of excipients).
- Patients taking any chronic medication should not use this product without consulting their medical practitioner.

4.4 Special warnings and precautions for use
- Must not be given to patients with known hypersensitivity or allergy towards any of the ingredients. Patients should be advised to consult their medical practitioner if in doubt.
- Linctagon® Junior Saline Nasal Spray contains erythritol which may cause a laxative effect.
- Do not exceed the daily recommended dose.
- Do not use after the date of expiry.
- Products containing herbal ingredients may interact with some medication.

Porphyria
Safety has not been established.
4.5 Interaction with other medicinal products and other forms of interaction
No interaction studies have been performed on Linctagon® Junior Saline Nasal Spray, see below interactions with individual ingredients.
No relevant interactions with other medications are anticipated considering the small quantity of the dose and the method of administration.
4.6 Fertility, pregnancy and lactation
Pregnancy
Must not be given during pregnancy as safety during pregnancy has not been established.
Breastfeeding
Must not be given during lactation as safety has not been established.
Fertility
There are no known effects of Linctagon® Junior Saline Nasal Spray on fertility.
4.7 Effects on the ability to drive and use machines.
Based on the side effect profile, Linctagon® Junior Saline Nasal Spray should not affect your ability to drive or operate machinery.
4.8 Undesirable effects
If any side effects or sensitivity to any of the ingredients are experienced, the use of this product should be discontinued.

Adverse events table		
System organ class	**Frequency**	**Adverse Events**
Respiratory, thoracic and mediastinal disorders	frequency unknown	Burning or stinging of the nose, increased nasal discharge, sneezing, unpleasant smell and taste.
Immune system disorders	frequency unknown	Hypersensitivity (allergic) reactions: difficulty breathing or swallowing, angioedema, itchy throat, urticaria and itching.

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://www.sahpra.org.za/Publications/Index/8
4.9 Overdose Symptoms
In overdose, side effects can be precipitated and/or be of increased severity.
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.
Erythritol
Erythritol is a four-carbon polyol. It has a very low insulin index, therefore, does not affect blood sugar or blood insulin levels.
Additionally, erythritol has shown potential in inhibiting the growth of certain pathogens.
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 rapidly absorbed in the proximal intestine.
Metabolism: Studies indicate that erythritol is oxidised to erythrose and later to erythronate.
Excretion: Erythritol is excreted rapidly through urine.
Sodium chloride
Absorption: Sodium chloride is well absorbed from the gastrointestinal tract.
Excretion: Excess sodium is excreted by the kidneys, while small amounts are also lost through faeces and urine.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Centrimide
Purified water
Linctagon® Junior Saline Nasal Spray contains a preservative: cetrimide 0,2 mg / ml.
Linctagon® Junior Saline Nasal Spray contains a sugar: erythritol 100 mg / ml.
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.
- Keep in original packaging until required for use.

6.5 Nature and contents of container
Linctagon® Junior Saline Nasal Spray is a clear solution.
Linctagon® Junior 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
To be allocated

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

10. DATE OF REVISION OF THE TEXT
March 2023

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