PROFESSIONAL INFORMATION
LINCTAGON® THROAT SPRAY

- Complementary Medicine
- Discipline: D 5.8 Preparations for the common cold including nasal decongestants.
- Claims – Combination Western Herbal Medicine
- 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® THROAT SPRAY

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

Active ingredients	Per 1 ml throat spray
Salvia officinalis fol Hab 3A	304 mg (101 mg plant material)
Pelargonium sidoides DC syrup cordial (extraction solvent ethanol 11%)	582 mg (128 mg plant material)

Each squirt = 0,12 ml.
Preservative: Alcohol 24 % (m/m), 31 % (v/v)
Linctagon® Throat Spray contains sugar (Fructose (17 mg/ml), glucose (17 mg/ml) and sucrose (28 mg/ml)).
Contains artificial sweeteners (Glycerine (57 mg/ml) and stevia (1 mg/ml))
For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Liquid throat spray

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
A combination throat spray for the relief of symptoms associated with colds and flu such as a sore throat, inflammation and pain when swallowing.

4.2 Posology and method of administration
Shake before use.
Adults and children 12 years and older:
Spray 6-8 squirts to the back of the throat, (3) three times per day.
Children between 6-12 years:
Spray 3-4 squirts to the back of the throat, (3) three times per day.
Advise patients to use for at least (5) five days to see beneficial effects.
The recommended duration of use is one (1) week.
Advise the patient to consult a healthcare provider if the symptoms do not improve within one (1) week of the use of this medicinal product.

4.3 Contraindications
- Hypersensitivity to any of the active substances or any other ingredients in Linctagon® Throat Spray (see 6.1 List of excipients).

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.
- Hepatotoxicity and hepatitis cases have been reported in association with the administration of products similar to Linctagon® Throat Spray. Advise patients to discontinue use in the event of signs of hepatotoxicity, and to consult a healthcare provider.
- Contains sucrose which may have an effect on the glycaemic control of patients with diabetes mellitus.
- Contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency should not take Linctagon® Throat Spray.
- Not suitable for children under the age of 2 years.
- Discontinue use two weeks prior to surgery.
- Patients of childbearing age, pregnant or breastfeeding see **4.6 Fertility, pregnancy and lactation**

Porphyria
Safety has not been established.

4.5 Interaction with other medicinal products and other forms of interaction

Active ingredient	Medicine	Description
Pelargonium sidoides	Anticoagulant medications	Due to the coumarin content, and the similarity thereof to warfarin (Coumadin), there is a theoretical possibility that *Pelargonium sidoides* might exert an anticoagulant effect.

4.6 Fertility, pregnancy and lactation
Pregnancy
Use during pregnancy is not recommended as safety during pregnancy has not been established.
Breastfeeding
Use is not recommended as safety during lactation has not been established.
Fertility
There are no known effects of Linctagon® Throat Spray on fertility.

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

4.8 Undesirable effects
Advice patients to discontinue use and consult a healthcare provider if they experience any side effects or sensitivity to any of the ingredients.

Organ system class	Frequency	Adverse Event
Blood and lymphatic system disorders	Rare	Minor epistaxis and gingival bleeding
Cardiac disorders	Unknown	Increase in body temperature and pulse rate
Gastrointestinal disorders	Unknown	Burning throat (mild), diarrhoea, gastrointestinal upset, nausea and vomiting, oral dryness.
	Rare	Dysphagia
Hepatobiliary disorders	Rare	Hepatotoxicity and hepatitis
Immune system disorders	Rare	Hypersensitivity reactions (conjunctivitis, rhinitis, bronchospasm, dyspnoea).
	Very rare	Hypersensitivity reactions (tachycardia, circulatory failure)
Respiratory, thoracic and mediastinal disorders	Unknown	Wheezing
Skin and subcutaneous tissue disorders	Rare	Hypersensitivity reaction (dermatitis, erythema, urticaria).

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

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
See **4.8 Undesirable effects**
No case of overdosage has been reported.
Advise patients not to exceed the recommended daily dosage.
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.
Complementary Medicines: Western Herbal Combination.
Pharmacotherapeutic classification: Throat preparations
ATC code: R02AX
Salvia officinalis:
The urisolic acid content of sage has displayed anti-inflammatory effects when applied topically. Carnosic acid and carnosol, constituents of sage preparations, have been shown to inhibit 5 lipoxygenase and suppress inflammatory responses of stimulated polymorphonuclear leukocytes. Another component of sage preparations, borneol, seems to decrease interleukin-1beta and interleukin-6 expression. Clinical research has shown that patients with acute pharyngitis or tonsillitis have experienced decreased symptoms of a sore throat when applying a combination throat spray containing sage for up to 5 days.
Pelargonium sidoides:
A study reported the in vitro antiviral activity of *Pelargonium sidoides* extract against influenza viruses. During this study, the abundance of the catechin polymer, prodelphinidin, in the extract resulted in the inhibition of influenza, and the impairment of viral haemagglutination and neuraminidase activity. Inhalation of *Pelargonium sidoides* extract has also been shown to enhance the survival of influenza-infected mice with the absence of obvious toxicity *Pelargonium sidoides* has been documented to provide symptomatic relief associated with the common cold. These symptoms include, among others, a scratchy or sore throat, hoarseness, rhinorrhoea, nasal irritation, sneezing and myalgia Poly phenols in *Pelargonium sidoides* (including catechin, gallocatechin, and gallic acid) are theorized to stimulate the release of tumor necrosis factor and interleukins, stimulate interferon activity, and increase the activity of natural killer cells. *Pelargonium* root extracts have also been shown to promote phagocytosis and decrease adhesion of bacteria to tissues.

5.2 Pharmacokinetic properties
Salvia officinalis :
Absorption: Preclinical research has shown that rosmarinic acid, a component of sage, is poorly absorbed across the intestinal wall. Sage monoterpenoids, including alpha-pinene and limonene, may penetrate the skin following topical application.
Metabolism: Alpha- and beta-thujone, components of sage, are metabolised by the liver to 4 – and 7-hydroxy-alpha-thujone, 4 hyroxy-beta-thujone and 7,8-dehydro-alpha-thujone.
Elimination: The hydroxylated metabolites are prone to second phase metabolism and excretion by glucuronidation.
Pelargonium sidoides :
Absorption: There is currently no information available on the biodistribution of *Pelargonium* extracts or their phytochemical constituents. However, the pharmacokinetics of the coumarin constituent has been investigated in a number of species, including humans, as a standalone pharmacophore. Studies performed on humans have shown that coumarin is completely absorbed from the gastrointestinal tract following oral administration. After absorption, coumarins undergo extensive first-pass metabolism in the liver with only 2 to 6 % reaching systemic circulation unchanged
Distribution: There is currently no information available on the biodistribution of *Pelargonium* extracts or their phytochemical constituents.
Metabolism: Studies have shown that, in humans, coumarin is metabolised, mainly by hepatic enzyme CYP2A6, to 7-hydroxycoumarin
Elimination: After administration of coumarin, 68-92% of the dose was recovered in the urine as 7-hydroxycoumarin glucuronide and sulfate conjugates
The rapid excretion into the urine suggests that in humans there is very little or no biliary excretion of coumarin metabolites

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Glycerol
Ethanol
Invert sugar syrup
Peppermint flavour mint 200519
Rebaudioside A (stevia)

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.
- Keep container tightly closed.
- Replace cap firmly after use.
- Protect from light and moisture.
- Keep in original packaging until required for use.
- Do not use after the expiry date printed on the carton and bottle.

6.5 Nature and contents of container
Linctagon® Throat Spray is a reddish-brown coloured solution
Linctagon® Throat Spray is packed into a 20 ml amber glass container with a white plastic spray nozzle cap, in a unit carton that includes a patient information leaflet.

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
To be allocated