PROFESSIONAL INFORMATION
LINCTAGON® NASAL SPRAY
- Complementary Medicine.
- D 5.8 Preparations for the common cold including nasal decongestants – Complementary Medicines: Western Herbal Combination Product.
- This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS
S0

1. NAME OF THE MEDICINE
LINCTAGON® NASAL SPRAY

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

Active ingredients	Per 1 ml	Per 2,4 ml (maximum daily dose)
Matricaria chamomilla L. (German chamomile) [flower, 10:1 extract in grapeseed oil providing 50 mg dried herb equivalent]	5 mg	12,2 mg
Eucalyptus globulus Labill. (Southern blue gum tree) [leaf, extract standardised to 75 % eucalyptol]	0,5 mg	1,2 mg
Cinnamomum camphora L. (Camphor tree) [bark, extract]	0,04 mg	0,1 mg

Linctagon® Nasal Spray contains a preservative: chlorobutanol 0,5 % m/m.
For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Liquid.
Linctagon® Nasal Spray is a white to cream coloured solution.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
Linctagon® Nasal Spray is a hypertonic nasal spray containing essential oils for the temporary relief of nasal congestion due to colds, sinusitis, hay fever or allergies.
4.2 Posology and method of administration
The recommended daily dosage and directions for use:

SHAKE BOTTLE BEFORE USE

Children 3-12 years old:
One (1) spray per nostril, maximum five (5) times per day.
Adults and children 12 years and older:
Two (2) sprays per nostril, maximum five (5) times per day.
Advise the patient not to exceed the maximum daily dose.
4.3 Contraindications
- Must not be given to patients with known hypersensitivity to any of the ingredients of Linctagon® 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 who have epilepsy or have chronic lung conditions as Linctagon® Nasal Spray contain camphor.
- Must not be given to patients who are pregnant or breastfeeding (see **4.6**).
- Linctagon® Nasal Spray is not suitable for children under the age of 3 years as it contains camphor.

4.4 Special warnings and precautions for use
- Linctagon® Nasal Spray may cause irritation or burning, advise patients to avoid direct contact with eyes.
- Advise patients not to exceed the daily recommended dose.
- Advise patients to use withing 2 weeks of opening.
- Advise patients not to 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 interactions
No interaction studies have been performed on Linctagon® Nasal Spray.
No relevant interactions with other medications are anticipated when considering the small quantity of the dose and the route of administration.
4.6 Fertility, pregnancy and lactation
Pregnancy
Safety of some of the ingredients for use during pregnancy has not been established. Camphor is specifically contraindicated; 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. Camphor is specifically contraindicated; therefore, this product should not be used if patients are lactating (breastfeeding).
Fertility
There are no known effects of Linctagon® Nasal Spray on fertility.
4.7 Effects on the ability to drive and use machines.
Based on the side effect profile, Linctagon® Nasal Spray should not affect the ability to drive or operate machinery.
4.8 Undesirable effects
Linctagon® 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
Immune system disorders	Not known	Hypersensitivity reactions or anaphylaxis, symptoms include: difficulty breathing or swallowing, angioedema, itchy throat, urticaria and itching.
Respiratory, thoracic and mediastinal disorders	Not known	Nose and sinus irritation.

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. Healthcare 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**
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 – Complementary Medicines: Western Herbal Combination Product.
Pharmacotherapeutic classification: Herbal medicinal product for treatment of symptoms associated with colds and flu.
ATC code: R02AX
Matricaria chamomilla
The medicinal part of German chamomile is the flowerhead, with active constituents including quercetin, apigenin, coumarins, matricin, chamazulene, alpha bisabolol and bisabolol oxides. German chamomile may possess anti-inflammatory properties; research suggests that it inhibits cyclooxygenase and lipoxygenase resulting in a decrease in the production of prostaglandins and leukotrienes. Quercetin and apigenin have shown to inhibit antigen stimulated mast cell degranulation and histamine release.
Eucalyptus globulus
The medicinal parts of eucalyptus are the leaves and their oil content, which includes litseagermacrane (a monocyclic sesquiterpenoid), prenylated phloroglucinols, methylated flavons, triterpenes and macrocarpals. The oil contains various terpenes including cineole, pinenes, phellandrene, and limonene. Eucalyptus oil consists of 60 % to 90 % eucalyptol. Research suggests that eucalyptol may inhibit the production of arachidonic acid metabolites that mediate pain. Eucalyptol might also inhibit cyclooxygenase pathways. Eucalyptus oil appears to inhibit the production of proinflammatory cytokines, such as tumor necrosis factor alpha, interleukin-1beta, leukotriene B4 and thromboxane B2. These properties may result in analgesic and anti-inflammatory pharmacological effects.
Cinnamomum camphora
The medicinal parts of the camphor tree are the bark and wood. Clinical research has suggested that camphor vapour inhalation does not affect nasal airflow resistance, however, subjects reported a cold sensation in the nose with the sensation of improved airflow.
5.2 Pharmacokinetic properties
Matricaria chamomilla
There is insufficient reliable data available concerning the pharmacokinetic characteristics of German chamomile and its constituents after nasal inhalation.
Eucalyptus globulus
Absorption: The constituent,1,8-cineol, is well absorbed via inhalation with the peak plasma level occurring at 18 minutes.
Elimination: The elimination of 1,8-cineol from the blood is biphasic, with a mean distribution half-life of 6,7 min and an elimination half-life of 104,6 min.
Cinnamomum camphora
Absorption: Camphor, a highly lipophilic molecule, is readily absorbed across mucous membranes and dermal tissue.
Distribution: Camphor possesses a large volume of distribution with significant partitioning to adipose tissue.
Metabolism: Camphor is oxidised to camphorol, with subsequent conjugation with glucuronide in the liver.
Excretion: Camphorol is highly lipophilic in nature and its partitioning in adipose tissue results in slow clearance. The majority of camphor and its metabolites are excreted in the urine.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Citric acid
Chlorobutanol
Hydroxyethylcellulose
Polysorbate 20
Potassium chloride
Purified water
Sodium chloride
Sodium citrate
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.
- Do not use after the expiry date printed on the carton.

6.5 Nature and contents of container
Linctagon® Nasal Spray is a white to cream coloured solution.
Linctagon® Nasal Spray is available in a 20 ml amber glass bottle with a metered-dose nozzle and is packaged in a printed unit carton which includes a patient information leaflet.
6.6 Special precautions for disposal and other handling
No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION
Nativa (Pty) Ltd
260 Cradock Avenue, Lyttelton, Centurion, 0157, Gauteng, South Africa
Tel: +27 (0) 12 664 7110
Customer care line: 0860 628 482
Email: health@nativa.co.za

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
November 2022

PPIL305/02