

PATIENT INFORMATION LEAFLET

Scheduling status:

S0

LINCTAGON® NASAL SPRAY

Matricaria chamomilla L. (Chamomile oil), Eucalyptus globulus Labill. (Eucalyptus oil), Cinnamomum camphora L. (Camphor oil).

Contains a preservative: chlorobutanol 0,5 % m/m.

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

Read all of this leaflet carefully because it contains important information for you.

Linctagon® Nasal Spray is available without a doctor's prescription. Nevertheless, you still need to use Linctagon® Nasal Spray carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Linctagon® Nasal Spray with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

WHAT IS IN THIS LEAFLET

1. What Linctagon® Nasal Spray is and what it is used for
2. What you need to know before you use Linctagon® Nasal Spray
3. How to use Linctagon® Nasal Spray
4. Possible side effects
5. How to store Linctagon® Nasal Spray
6. Contents of the pack and other information

1. What Linctagon® Nasal Spray is and what it is used for

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.

2. What you need to know before you use Linctagon® Nasal Spray

Do not use Linctagon® Nasal Spray:

- If you are hypersensitive (allergic) to any of the ingredients of Linctagon® Nasal Spray (listed in section 6 **Contents of pack and other information**).
- If you have epilepsy (suffer from seizures) or a chronic lung condition (e.g., asthma) as Linctagon® Nasal Spray contains camphor.
- If you are pregnant or breastfeeding (see **Pregnancy, breastfeeding and fertility**).
- Linctagon® Nasal Spray is not suitable for children under the age of 3 years as it contains camphor.

Warnings and precautions

Special care should be taken with Linctagon® Nasal Spray:

- Linctagon® Nasal Spray may cause irritation or burning; avoid direct contact with eyes.
- Do not exceed the daily recommended dose.
- Do not use after the date of expiry.

Porphyria: Safety has not been established.

Tell your doctor if you are not sure about any of the above.

Other medicines and Linctagon® Nasal Spray

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Linctagon® Nasal Spray has no known interactions with other medications.

Using Linctagon® Nasal Spray with food, drink and alcohol

There is no known interaction between the contents of Linctagon® Nasal Spray and food, drink and alcohol.

Pregnancy, breastfeeding and fertility

Do not use Linctagon® Nasal Spray if you are pregnant or breastfeeding as it contains camphor which is contraindicated.

Driving and using machinery

Linctagon® Nasal Spray should not affect your ability to drive or use machinery. However, if you think you are affected you should not drive or operate machinery until you feel better.

3. How to use Linctagon® Nasal Spray

Do not share medicines with any other person.

Always use Linctagon® Nasal Spray exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. You should check with your doctor, pharmacist or nurse if you are unsure .

SHAKE BOTTLE BEFORE USE

The usual dose for children from 3 to 12 years:

Spray one (1) spray in each nostril, maximum five (5) times per day.

The usual dose for adults and children 12 years and older is:

Spray two (2) sprays in each nostril, maximum five (5) times per day.

Do not exceed the daily recommended dose.

If you use more Linctagon® Nasal Spray than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison center.

If you forget to use Linctagon® Nasal Spray

Use your missed dose when you remember. Do not use a double dose to make up for forgotten individual doses.

If you stop using Linctagon® Nasal Spray

If you are using the dose as indicated, it is unlikely that there should be withdrawal effects when you stop using this medication.

4. Possible side effects

Linctagon® Nasal Spray can have side effects.

Not all side effects reported for Linctagon® Nasal Spray are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking Linctagon® Nasal Spray, please consult your healthcare provider for advice.

If any of the following happens, stop taking Linctagon® Nasal Spray and consult your doctor immediately or go to the casualty department at your nearest hospital:

Allergic reactions such as: skin rashes, hives (skin bumps), itchiness, swelling of the face, lips mouth or throat, which may cause difficulty in swallowing or breathing.

These are all very serious side effects. If you have them, you may have had a serious reaction to Linctagon® Nasal Spray. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice any of the following:

Frequency not known:

- Nose and sinus irritation.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of Linctagon® Nasal Spray.

5. How to store Linctagon® Nasal Spray

- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Store in a dry place at or below 25 °C.
- Protect from light.
- Do not use after the expiry date stated on the label and carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of pack and other information

What Linctagon® Nasal Spray contains

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

The other ingredients are: citric acid, hydroxyethylcellulose, polysorbate 20, potassium chloride, purified water, sodium chloride, sodium citrate.

Linctagon® Nasal Spray contains a preservative: chlorobutanol 0,5 % m/m.

What Linctagon® Nasal Spray looks like and contents of the pack

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.

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

Website: www.nativa.co.za

This leaflet was last revised in

November 2022

Date of registration

To be allocated

Registration number

To be allocated

Professional Information

The Linctagon® Nasal Spray Professional Information may be obtained from the Nativa website (www.nativa.co.za).