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)**
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 oil) [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

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

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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).

PASIËNTINLIGTINGSBROSJURE

Skeduleringstatus:
S0

LINCTAGON® NASAL SPRAY (neussproei)
Matricaria chamomilla L. (Kamille-olie), *Eucalyptus globulus* Labill. (Bloekomolie), *Cinnamomum camphora* L. (Kamfer-olie).
Bevat 'n preserveermiddel: chloorbutanol 0,5 % m/m.
- D.5.8 Preparate vir verkoue insluitend nasale dekongestante - Komplementêre Medisyne: Westerse Kruie Kombinasie Produk.
- Hierdie medisyne is nog nie deur die SAHPRA geregistreer of geëvalueer vir kwaliteit, veiligheid of voorgestelde gebruik nie.

Lees die hele brosjure deeglik want dit bevat belangrike inligting.
Linctagon® Nasal Spray is beskikbaar sonder 'n dokter se voorskrif. U moet egter steeds Linctagon® Nasal Spray met omsigtigheid gebruik om die beste resultate daarmee te verkry.
- Hou hierdie brosjure. Dit kan nodig wees dat u dit weer moet lees.
- Moet nie Linctagon® Nasal Spray met enige ander persoon deel nie.
- Indien u verdere inligting of advies verlang, vra asseblief u gesondheidsorgverskaffer of apteker.

WAT IS IN HIERDIE BROSJURE
1. Wat Linctagon® Nasal Spray is en waarvoor dit gebruik word
2. Wat u moet weet voordat u Linctagon® Nasal Spray gebruik.
3. Hoe om Linctagon® Nasal Spray te gebruik
4. Moontlike newe-effekte
5. Hoe om Linctagon® Nasal Spray te bewaar
6. Inhoud van die verpakking en ander inligting

1. Wat Linctagon® Nasal Spray is en waarvoor dit gebruik word
Linctagon® Nasal Spray is 'n hipertoniese neussproei wat essensiële olies bevat vir die tydelike verligting van 'n toe neus as gevolg van verkoue, sinusitis, hooikoors of allergieë.

2. Wat u moet weet voordat u Linctagon® Nasal Spray gebruik
Moet nie Linctagon® Nasal Spray gebruik nie:
- Indien u hipersensitief (allergies) is vir enige van die bestanddele in Linctagon® Nasal Spray (gelys in afdeling 6 **Inhoud van die verpakking en ander inligting**).
- Indien u epilepsie (stuipe) of 'n kroniese longtoestand het (bv. asma), aangesien Linctagon® Nasal Spray kamfer bevat.
- Indien u swanger is of borsvoed (sien **Swangerskap, borsvoeding en vrugbaarheid**).
- Linctagon® Nasal Spray is nie geskik vir kinders sonder die ouderdom van 3 jaar nie, aangesien dit kamfer bevat.

Waarskuwings en voorsorgmaatreëls
Noukeurige sorg behoort geneem te word met Linctagon® Nasal Spray:
- Linctagon® Nasal Spray kan irritasie en brand veroorsaak; vermy direkte kontak met oë.
- Moet nie die voorgeskrewe daaglikse dosis oorskry nie.
- Moet nie na die vervaldatum gebruik nie.

Porfirie: Veiligheid is nog nie vasgestel nie.
U moet u dokter raadpleeg indien u onseker is van enige van die bogenoemde.

Ander medikasie en Linctagon® Nasal Spray
Lig altyd u gesondheidsorgverskaffer in wanneer u medisyne op 'n gereelde basis neem, insluitend komplementêre- of tradisionele-medisyne.
Linctagon® Nasal Spray het geen bekende interaksies met ander medikasies nie.

Gebruik van Linctagon® Nasal Spray saam met kos, drinkgoed en alkohol
Daar is geen bekende interaksie tussen die inhoud van Linctagon® Nasal Spray en kos, drinkgoed en alkohol nie.

Swangerskap, borsvoeding en vrugbaarheid
Moet nie Linctagon® Nasal Spray gebruik indien u swanger is of borsvoed nie, aangesien dit kanfer bevat wat teen aangedui is.

Bestuur en die gebruik van masjinerie
Linctagon® Nasal Spray behoort nie u vermoë om te bestuur of masjinerie te gebruik, te beïnvloed nie. Indien u egter dink dat u aangetas is, moet u nie bestuur of masjiene gebruik voordat u beter voel nie.

3. Hoe om Linctagon® Nasal Spray te gebruik
Moet nie u medisyne met enige ander persoon deel nie.
Gebruik Linctagon® Nasal Spray altyd presies soos voorgeskryf in hierdie brosjure of soos u dokter, apteker of verpleegster u aanbeveel het. Maak asseblief seker by u dokter, apteker of verpleegster wat die aanbevole dosis is indien u onseker is.

SKUD DIE BOTTLE VOOR GEBRUIK

Die gewone dosis vir kinders van 3 tot 12 jaar:
Spuit een (1) spuit in elke neusgat, maksimum (5) keer per dag.
Die gewone dosis vir volwassenes en kinders 12 jaar en ouer is:
Spuit twee (2) spuite in elke neusgat, maksimum vyf (5) keer per dag.
Moet nie die voorgeskrewe daaglikse dosis oorskry nie.

Indien u meer Linctagon® Nasal Spray gebruik het as wat u moes
In die geval van 'n oordosis, raadpleeg u dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien u vergeet om Linctagon® Nasal Spray te gebruik
Gebruik die dosis wat oorgeslaan is, sodra u daarvan onthou. Moet nie 'n dubbele dosis gebruik om te vergoed vir individuele dosisse wat u oorgeslaan het nie.

Wanneer u ophou om Linctagon® Nasal Spray te gebruik
Indien u die dosis gebruik soos aangedui, sal daar waarskynlik geen ontrekkingseffek wees wanneer u die gebruik van hierdie medikasie staak nie.

4. Moontlike newe-effekte
Linctagon® Nasal Spray kan newe-effekte hê.
Nie alle newe-effekte wat aangemeld is vir Linctagon® Nasal Spray is in hierdie brosjure ingesluit nie. Indien u algemene gesondheid vererger, of indien u ongewenste gevolge ervaar tydens die gebruik van Linctagon® Nasal Spray, raadpleeg u gesondheidsorgverskaffer vir advies.

Indien een van die volgende newe-effekte voorkom, hou op Linctagon® Nasal Spray te gebruik en raadpleeg u dokter onmiddellik of gaan na die naaste ongevalle-afdeling by u naaste hospitaal:
Allergiese reaksies soos: veluitslag, knoppe (velbultjies), jeukerigheid, swelling van die gesig, lippe, mond of keel, wat probleme met sluk of asemhaling kan veroorsaak.
Hierdie is almal baie ernstige newe-effekte. Indien u dit ervaar, het u dalk 'n ernstige reaksie op Linctagon® Nasal Spray gehad. U mag dalk dringende mediese aandag of hospitalisasie benodig.

Vertel u dokter of apteker indien u enige van die volgende waarneem:
Frekwensie nie-bekend:
- Neus- en sinus-irritasie.

Lig asseblief u dokter of apteker in indien u enige newe-effekte opmerk wat nie in hierdie brosjure genoem word nie.

Rapportering van newe-effekte
Praat met u dokter, apteker, of verpleegster indien u newe-effekte ervaar. U kan ook newe-effekte by SAHPRA aanmeld via die "**6.04 Adverse Drug Reaction Reporting Form**", wat aanlyn gevind kan word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan u help om meer inligting rakende die veiligheid van Linctagon® Nasal Spray te verskaf.

5. Hoe om Linctagon® Nasal Spray te bewaar
- BEWAAR ALLE MEDISYNE BUITE DIE BEREIK VAN KINDERS.
- Bewaar in 'n droë plek by of benede 25 °C.
- Beskerm teen lig.
- Moet nie ná die vervaldatum op die verpakking gebruik nie.
- Neem alle ongebruikte medisyne terug na u apteker.
- Moet nie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting
Wat Linctagon® Nasal Spray bevat

Aktiewe bestanddele	**Per 1 ml**	**Per 2,4 ml (maksimum daaglikse dosis)**
Matricaria chamomilla L. (Duitse kamille) [blom, 10:1 uittreksel in druiwepit olie verskaf 50 mg gedroogte krui-ekwivalent]	5 mg	12,2 mg
Eucalyptus globulus Labill. (Suidelike bloekomboom olie) [blaar, uittreksel gestandaardiseerd tot 75 % eucalyptol]	0,5 mg	1,2 mg
Cinnamomum camphora L. (Kanferboom) [bas, uittreksel]	0,04 mg	0,1 mg

Die ander bestanddele is: sitroensuur, hidroksietielsellulose, polisorbaat 20, kaliumchloried, gesuiwerde water, natriumchloried, natriumsitraat.
Linctagon® Nasal Spray bevat 'n preserveermiddel: chloorbutanol 0,5 % m/m.

Hoe Linctagon® Nasal Spray lyk en die inhoud van die verpakking
Linctagon® Nasal Spray is 'n wit - tot roomkleurige oplossing.
Linctagon® Nasal Spray is beskikbaar in 'n 20 ml amberkleurige glasbottel met 'n afgemete dosis spuitkopdop en is verpak in 'n gedrukte eenheidskarton wat 'n pasiëntinligtingsbrosjure insluit.

Houer van Sertifikaat van Registrasie
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Hierdie brosjure was laas hersien in
November 2022

Datum van registrasie
Moet toegeken word

Registrasienommer
Moet toegeken word

Professionele Inligting
Die Linctagon® Nasal Spray Professionele Inligting kan verkry word op die Nativa webwerf (www.nativa.co.za).