

PATIENT INFORMATION LEAFLET

Scheduling status:

SO

LINCTAGON® SALINE NASAL SPRAY

Erythritol, Sodium chloride.

Contains sugar: Erythritol 100 mg/ml.

- **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.

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

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

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

WHAT IS IN THIS LEAFLET

- What Linctagon® Saline Nasal Spray is and what it is used for.
- What you need to know before you take Linctagon® Saline Nasal Spray.
- How to take Linctagon® Saline Nasal Spray.
- Possible side effects.
- How to store Linctagon® Saline Nasal Spray.
- Contents of the pack and other information.

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

A hypertonic nasal spray for the temporary relief of nasal congestion due to colds, sinusitis, hay fever or allergies. Linctagon® Saline Nasal Spray can act as a nasal irrigator and moisturiser.

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

Do not take Linctagon® Saline Nasal Spray:

- If you are hypersensitive (allergic) to any of the ingredients of Linctagon® Saline Nasal Spray (listed in section **6 Contents of pack and other information**).
- If you have a rare hereditary condition of erythritol-intolerance.

Warnings and precautions

- Linctagon® Saline Nasal Spray contains erythritol, which may have a laxative effect.
- Do not exceed the daily recommended dose.
- Do not use after the date of expiry.
- Use within 30 days of opening.

Porphyria: Safety has not been established.

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

Other medicines and Linctagon® Saline Nasal Spray

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

Consult your doctor, pharmacist or healthcare provider before use if you are taking:

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

Taking Linctagon® Saline Nasal Spray with food and drink

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

Pregnancy and Breastfeeding

Do not use Linctagon® Saline Nasal Spray if you are pregnant or breastfeeding as safety has not been established.

Driving and using machinery

Linctagon® Saline 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 take Linctagon® Saline Nasal Spray

Do not share medicines with any other person.

Always take Linctagon® Saline Nasal Spray exactly as described in this leaflet or as your healthcare provider has instructed you. You should check with your doctor or pharmacist if you are unsure. Clear the nasal passageway by gently blowing your nose before use.

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

Spray two (2) sprays in each nostril, three (3) times per day or use as required to cleanse the nasal passages and sinuses.

The usual dose for children between 2 – 12 years:

Spray one (1) spray in each nostril, three (3) times per day or use as required to cleanse the nasal passages and sinuses.

If you take more Linctagon® Saline 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 take Linctagon® Saline Nasal Spray

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

If you stop taking Linctagon® Saline Nasal Spray

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

4. Possible side effects

Linctagon® Saline Nasal Spray can have side effects.

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

If any of the following or other side effects occur, stop taking this product and consult your doctor or pharmacist or go to the casualty department at your nearest hospital: Allergic reactions such as: skin ashes, hives (skin bumps), itchiness, swelling of the face, lips mouth or throat, which may cause difficulty in swallowing or breathing.

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

Frequency unknown:

- Burning or stinging of the nose, increased nasal discharge, sneezing, unpleasant smell and taste.
- 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://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf.

By reporting side effects, you can help provide more information on the safety of Linctagon® Saline Nasal Spray.

5. How to store Linctagon® Saline Nasal Spray

- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- in a dry place at or below 25 °C.
- Protect from light.
- Do not refrigerate.
- Do not store in a bathroom.
- 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® Saline Nasal Spray contains

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

Linctagon® Saline Nasal Spray contains preservative: Cetrimide 0,2 mg/mL

Linctagon® Saline Nasal Spray contains sugar: Erythritol 100 mg/ml.

Other ingredients are: Cetrimide, purified water.

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

Linctagon® Saline Nasal Spray is a clear solution.

Linctagon® 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.

Holder of Certificate of Registration

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This leaflet was last revised in
July 2022.

Date of registration

To be allocated.

Registration number

To be allocated.

Professional Information

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