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2021/06

PATIENT INFORMATION LEAFLET**Scheduling status:****S0****LINCTAGON®-C JUNIOR COLD AND FLU SYRUP**

Pelargonium sidoides root extract, Vitamin A (vitamin A retinyl palmitate), Vitamin C (ascorbic acid), MSM (methylsulfonylmethane), Zinc (zinc gluconate)
Contains artificial sweeteners: sorbitol 2 g / 5 ml, sucralose 2,5 mg / 5 ml, xylitol 0,46 g / 5 ml.

- Complementary Medicine: 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®-C Junior Cold and Flu Syrup is available without a doctor's prescription. However, you still need to use Linctagon®-C Junior Cold and Flu Syrup carefully to get the best results from it.

- Keep this leaflet. You may need to read it again
- Do not share Linctagon®-C Junior Cold and Flu Syrup 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®-C Junior Cold and Flu Syrup is and what it is used for.
2. What you need to know before you take Linctagon®-C Junior Cold and Flu Syrup.
3. How to take Linctagon®-C Junior Cold and Flu Syrup.
4. Possible side effects.
5. How to store Linctagon®-C Junior Cold and Flu Syrup.
6. Contents of the pack and other information.

1. What Linctagon®-C Junior Cold and Flu Syrup is and what it is used for

Linctagon®-C Junior Cold and Flu Syrup is a combination syrup for the relief of symptoms associated with the common cold and flu such as congestion, sneezing, allergies, coughs, muscle aches and with immune support. Contains high levels of vitamin C.

2. What you need to know before you take Linctagon®-C Junior Cold and Flu Syrup**Do not take Linctagon®-C Junior Cold and Flu Syrup:**

- If you are hypersensitive (allergic) to any of the ingredients of Linctagon®-C Junior Cold and Flu Syrup (listed in section 6).

Warnings and precautions

- Use with caution if you have or are prone to iron overload, hemochromatosis, thalassemia and sideroblastic anaemia as Linctagon®-C Junior Cold and Flu Syrup contains vitamin C which can increase iron absorption and may worsen these conditions.
- Use with caution if you have a history of oxalate kidney stones as Linctagon®-C Junior Cold and Flu Syrup contains vitamin C which can increase the risk of stone formation.
- Linctagon®-C Junior Cold and Flu Syrup contains sorbitol. If you have been told that you have an intolerance to some sugars, you should not take Linctagon®-C Junior Cold and Flu Syrup.
- Discontinue use two weeks before planned surgery.

Porphyria: Safety has not been established.

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

Other medicines and Linctagon®-C Junior Cold and Flu Syrup

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 using Linctagon®-C Junior Cold and Flu Syrup if you are taking:

- Blood thinning medication such as warfarin or antiplatelet medication such as clopidogrel, as *Pelargonium sidoides* root extract may have a blood thinning effect.
- Vitamin A supplements or other retinoid medications, as Linctagon®-C Junior Cold and Flu Syrup contains vitamin A and using these together could result in an overdose of vitamin A.
- Diclofenac, as Linctagon®-C Junior Cold and Flu Syrup may increase the effects and side effects of diclofenac.
- Tetracycline antibiotics as Linctagon®-C Junior Cold and Flu Syrup contains zinc which may reduce the absorption of antibiotics. Oral antibiotics should be taken at least two (2) hours before, or four (4) hours after Linctagon®-C Junior Cold and Flu Syrup or similar supplements.
- Warfarin as Linctagon®-C Junior Cold and Flu Syrup contains a high dose of vitamin C which may reduce the response to warfarin, possibly by causing diarrhoea and reducing warfarin absorption.

Taking Linctagon®-C Junior Cold and Flu Syrup with food and drink

There is no known interaction between the contents of Linctagon®-C Junior Cold and Flu Syrup and food or drink.

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding, think you might be pregnant or are planning to have a baby, please consult your doctor or pharmacist or other healthcare provider for advice before taking this medication.

Driving and using machinery

Linctagon®-C Junior Cold and Flu Syrup 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®-C Junior Cold and Flu Syrup

Do not share medicines with any other person.

Always take Linctagon®-C Junior Cold and Flu Syrup 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.

The usual dose for children 6 – 12 years old is:

Give one (1) medicine measure (5 ml) three times a day, after a meal.

The usual dose for children 2 – 6 years old is:

Give one (1) medicine measure twice per day, after a meal.

Give (4) four hours before or (2) two hours after taking other medications (see **Other medicines with Linctagon®-C Junior Cold and Flu Syrup**)

The recommended duration of use is one (1) week.

If you take more Linctagon®-C Junior Cold and Flu Syrup than you should

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

If you forget to take Linctagon®-C Junior Cold and Flu Syrup

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®-C Junior Cold and Flu Syrup

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®-C Junior Cold and Flu Syrup can have side effects

Not all side effects reported for Linctagon®-C Junior Cold and Flu Syrup 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.

Like all medicines, this medicine can cause side effects, although not everybody will experience them.

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 rash and itching, runny nose and red eyes, fast heartbeat and difficulty breathing.

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

Frequency unknown:

- Diarrhoea, dry mouth, heartburn, indigestion, mouth irritation, nausea, stomach upset, vomiting.

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®-C Junior Cold and Flu Syrup.

5. How to store Linctagon®-C Junior Cold and Flu Syrup

- STORE ALL MEDICINES OUT OF REACH OF CHILDREN
- Store in a dry place at or below 25 °C.
- Protect from light and moisture
- 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®-C Junior Cold and Flu Syrup contains**

Active ingredients	Per 5 ml syrup	Per 15 ml syrup (max daily dosage)	% NRV* per 15 ml syrup (max daily dosage)
<i>Pelargonium sidoides</i> [dried root extract] from the roots of <i>Pelargonium sidoides</i> DC (1:8-10) Pelapower™ EMA 11-70. Extraction solvent ethanol 11 % w/w.	6,67 mg	20,01 mg	*
Vitamin A (vitamin A retinyl palmitate 250000 IU/ g)	333 IU (100 µg)	999 IU (300 µg)	33,34
Vitamin C (ascorbic acid)	267 mg	801 mg	800
MSM (methylsulfonylmethane)	134 mg	402 mg	*
Zinc (zinc gluconate)	1,67 mg	5,01 mg	45,45

Nutrient Reference Values for adults and children older than 4 years.

* NRV not established

The other ingredients are: cherry-berry flavour, glycerine, pelargonium in glycerine, potassium sorbate, RO water, sodium carboxymethylcellulose, sorbitol, sucralose, xylitol.

Linctagon®-C Junior Cold and Flu Syrup is sugar and alcohol free.

Linctagon®-C Junior Cold and Flu Syrup contains artificial sweeteners.

What Linctagon®-C Junior Cold and Flu Syrup looks like and contents of the pack

Linctagon®-C Junior Cold and Flu Syrup is a light, yellow-caramel liquid with a cherry-berry aroma and flavour.

Linctagon®-C Junior Cold and Flu Syrup is packed into a 100 ml and 200 ml amber glass container with a white plastic cap, in a unit carton that includes a patient information leaflet.

Holder of Certificate of Registration

Nativa (Pty) Ltd

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This leaflet was last revised in

February 2021

Date of registration

To be allocated

Registration number

To be allocated

Professional Information

The Linctagon®-C Junior Cold and Flu Syrup Professional Information may be obtained from the Nativa website (www.nativa.co.za).

PASIËNTINLIGTINGSBROSJURE

Skeduleringsstatus:

S0

LINCTAGON®-C JUNIOR COLD AND FLU SYRUP

Pelargonium sidoides wortelekstrak, Vitamien A (vitamien A retinielpalmitaat), Vitamien C (askorbiensuur), MSM (metielsulfonietaan), Sink (sinkglukonaat).
Bevat kunsmatige versoeters: sorbitol 2 g / 5 ml, sukrulose 2,5 mg / 5 ml, xilitol 0,46 g / 5 ml.
• Komplementêre Medisyne: Prepareate vir verkoue insluitend neusontstuwende-middels.
• Hierdie medisyne is nog nie deur die SAHPRA geregistreer of geëvalueer vir kwaliteit, veiligheid of voorgestelde gebruik nie.

Lees die hele inligtingsblad deeglik want dit bevat belangrike inligting.

Linctagon®-C Junior Cold and Flu Syrup is beskikbaar sonder 'n dokter se voorskrif. U moet egter steeds Linctagon®-C Junior Cold and Flu Syrup versigtig gebruik om die beste resultate daarmee te verkry.
• Hou hierdie inligtingsblad. Dit kan nodig wees dat u dit weer moet lees
• Moet nie Linctagon®-C Junior Cold and Flu Syrup met enige ander persoon deel nie
• Indien u verdere inligting of advies verlang, vra asseblief u gesondheidsorgverskaffer of apteker.

WAT IS IN HIERDIE VOUBILJET

1. Wat Linctagon®-C Junior Cold and Flu Syrup is en waarvoor dit gebruik word .
2. Wat u moet weet voordat u Linctagon®-C Junior Cold and Flu Syrup neem.
3. Hoe om Linctagon®-C Junior Cold and Flu Syrup te neem.
4. Moontlike nuwe-effekte.
5. Hoe om Linctagon®-C Junior Cold and Flu Syrup te bewaar.
6. Inhoud van die verpakking en ander inligting.

1. Wat Linctagon®-C Junior Cold and Flu Syrup is en waarvoor dit gebruik word

Linctagon®-C Junior Cold and Flu Syrup is 'n kombinasie stroop vir die verligting van simptome geassosieer met verkoue en griep soos toe-neus, niesbuie, allergieë, hoes en seer spiëre met immuunondersteuning. Bevat hoë vitamien C vlakke.

2. Wat u moet weet voordat u Linctagon®-C Junior Cold and Flu Syrup neem

Moet nie Linctagon®-C Junior Cold and Flu Syrup neem nie:

• Indien u hipersensitief (allergies) is vir enige van die bestanddele in Linctagon®-C Junior Cold and Flu Syrup (gelys in afdeling 6).

Waarskuwings en voorsorgmaatreëls

• Gebruik die produk versigtig indien u geneig is tot ysteroorlading, of hemochromatose, thalassemie en sideroblastiese anemie het, aangesien Linctagon®-C Junior Cold and Flu Syrup vitamien C bevat wat ysterabsorpsie kan verhoog en hierdie toestande kan vererger.
• Gebruik die produk versigtig indien u 'n geskiedenis van oksalaat-nierstene het, aangesien Linctagon®-C Junior Cold and Flu Syrup vitamien C bevat wat die risiko van niersteen-vorming kan verhoog.
• Linctagon®-C Junior Cold and Flu Syrup bevat. Indien daar aan u gesê is dat u 'n onverdraagsaamheid het tot sommige suikers, moet u nie Linctagon®-C Junior Cold and Flu Syrup gebruik nie
• Staak gebruik twee weke voor enige beplande operasie.

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®-C Junior Cold and Flu Syrup

Lig altyd u gesondheidsorgverskaffer in wanneer u medisyne op 'n gereelde basis neem, insluitend komplementêre- of tradisionele- medisyne. Raadpleeg u dokter, apteker of gesondheidsorgverskaffer indien u Linctagon®-C Junior Cold and Flu Syrup in kombinasie met die volgende medisyne wil gebruik:

• Bloedverduunnings medikasie soos warfarin of anti-plaatjie medikasie soos klopidoogrel, aangesien *Pelargonium sidoides* wortel ekstrak 'n bloedverduunnings effek kan hê.
• Vitamien A aanvullings of ander retinoïed medikasies, aangesien Linctagon®-C Junior Cold and Flu Syrup vitamien A bevat en die gebruik van dié saam kan lei tot 'n oordosis van vitamien A.
• Diklofenak, aangesien Linctagon®-C Junior Cold and Flu Syrup die effek en nuwe effekte kan vererger.
• Tetrasiklien antibiotika, aangesien Linctagon®-C Junior Cold and Flu Syrup Sink bevat, wat die absorpsie van antibiotika kan verlaag. Orale antibiotika moet ten minste twee (2) ure voor of vier (4) ure na Linctagon®-C Junior Cold and Flu Syrup geneem word.
• Warfarin, aangesien Linctagon®-C Junior Cold and Flu Syrup hoë hoeveelhede Vitamien C bevat wat die respons tot warfarin kan verlaag, moontlik deur diarree te veroorsaak en die absorpsie van warfarin te verlaag.

Neem van Linctagon®-C Junior Cold and Flu Syrup saam met kos en drinkgoed

Daar is geen bekende interaksie tussen die inhoud van Linctagon®-C Junior Cold and Flu Syrup en eet- of drinkgoed nie.

Swangerskap en borsvoeding

Indien u swanger is, u baba borsvoed, dink dat u is swanger of beplan om swanger te raak, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u hierdie medisyne neem.

Bestuur en die gebruik van masjinerie

Linctagon®-C Junior Cold and Flu Syrup 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 masjinerie gebruik voordat u beter voel nie.

3. Hoe om Linctagon®-C Junior Cold and Flu Syrup te neem

Moet nie u medisyne met enige ander persoon deel nie.

Neem Linctagon®-C Junior Cold and Flu Syrup altyd presies soos voorgeskryf in hierdie voubiljet of soos u gesondheidsorgverskaffer u aanbeveel het. Maak asseblief seker by u dokter of apteker wat die aanbevole dosis is indien u onseker is.

Die gewone dosis vir kinders 6 - 12 jaar oud is:

Gee een (1) medisynemaat (5 ml) drie keer per dag, na ete.

Die gewone dosis vir kinders 2 - 6 jaar oud is:

Gee een (1) medisynemaat (5 ml) twee keer per dag, na ete.

Gee (4) vier ure voor of (2) twee ure na ander medikasie (sien **Ander medisyne saam met Linctagon®-C Junior Cold and Flu Syrup**)

Die voorgestelde tydperk van gebruik is een (1) week.

Indien u meer Linctagon®-C Junior Cold and Flu Syrup geneem 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®-C Junior Cold and Flu Syrup te neem

Neem die dosis wat oorgeslaan is, sodra u daarvan onthou. Moet nie 'n dubbele dosis neem om te vergoed vir individuele dosisse wat u oorgeslaan het nie.

Wanneer u stop om Linctagon®-C Junior Cold and Flu Syrup te gebruik

Indien u die dosis neem soos aangedui, sal daar waarskynlik geen onttrekkingseffek wees wanneer u die gebruik van hierdie medikasie staak nie.

4. Moontlike nuwe-effekte

Linctagon®-C Junior Cold and Flu Syrup kan nuwe-effekte hê.

Nie alle nuwe-effekte wat aangemeld is vir Linctagon®-C Junior Cold and Flu Syrup is in hierdie voubiljet ingesluit nie. Indien u algemene gesondheid vererger, of indien u ongewenste gevolge ervaar tydens die gebruik van hierdie medikasie, raadpleeg u gesondheidsorgverskaffer vir advies.
Soos alle medisyne, kan hierdie medisyne nuwe-effekte veroorsaak, alhoewel nie almal dit gaan ervaar nie.

Indien een van die volgende of ander nuwe-effekte voorkom, stop die gebruik van hierdie produk en raadpleeg u dokter of apteker of gaan na die naaste ongevalle-afdeling by u naaste hospitaal:

Allergiese reaksies soos: veluitslag en jeuk, loop-neus en rooi oë, vinnige hartklop en moeilike asemhaling.

Vertel u dokter of apteker indien u enige van die volgende waarneem:

Frekwensie onbekend:

• Diarree, droë mond, sooibrand, slegte spysvertering, mond irritasie, naarheid, maag ongesteldheid en braking.

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

Rapportering van nuwe-effekte

Praat met u dokter, apteker, of verpleegster indien u nuwe-effekte ervaar. U kan ook nuwe-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 nuwe-effekte aan te meld, kan u help om meer inligting rakende die veiligheid van Linctagon®-C Junior Cold and Flu Syrup te verskaf.

5. Hoe om Linctagon®-C Junior Cold and Flu Syrup te bewaar

• BEWAAR ALLE MEDISYNE BUITE DIE BEREIK VAN KINDERS.
• Bewaar in 'n droë plek by of benede 25 °C.
• Beskerm teen lig en vog.
• Moet nie in die yskas verkoel nie.
• Moet nie in die badkamer stoor nie.
• 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®-C Junior Cold and Flu Syrup bevat

Aktiewe bestanddele	Per 5 ml stroop	Per 15 ml stroop (mask daaglikse dosis)	% VVW* per 15 ml stroop (maks daaglikse dosis)
<i>Pelargonium sidoides</i> [gedroogde wortelekstrak] van die wortels van <i>Pelargonium sidoides</i> DC (1:8-10) Pelapower™ EMA 11-70. Ekstraksie-oplosmiddel etanol 11% w/w.	6,67 mg	20,01 mg	*
Vitamien A (vitamien A retinielpalmitaat 250000 IU / g)	333 IU (100 µg)	999 IU (300 µg)	33,34
Vitamien C (askorbiensuur)	267 mg	801 mg	800
MSM (metielsulfonietaan)	134 mg	402 mg	*
Sink (sinkglukonaat)	1,67 mg	5,01 mg	45,45

Voedingsverwysings waardes vir volwassenes en kinders ouer as 4 jaar.

* VVW nie bevestig nie

Die ander bestanddele is: kersie-bessiegeur, gliserien, pelargonium in gliserien, kaliumsorbaat, RO water ,natrium-karboksiemetiellulose, sorbitol, sukrulose, xylitol.

Linctagon®-C Junior Cold and Flu Syrup is suiker en alkohol vry.
Linctagon®-C Junior Cold and Flu Syrup bevat kunsmatige versoeters.

Hoe Linctagon®-C Junior Cold and Flu Syrup lyk en die inhoud van die verpakking

Linctagon®-C Junior Cold and Flu Syrup is 'n ligte, geel-karamel vloeistof met 'n kersie-bessiereuk en -geur.

Linctagon®-C Junior Cold and Flu Syrup is verpak in 100 ml en 200 ml amber glashouers met 'n wit plastiekprop, in 'n eenheidskarton wat 'n pasiëntinligtingsbrosjure insluit.

Houer van Sertifikaat van Registrasie

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Hierdie voubiljet was laas hersien in

February 2021

Datum van registrasie

Moet toegeken word

Registrasienuommer

Moet toegeken word

Professionele Inligting

Die Linctagon®-C Junior Cold and Flu Syrup Professionele Inligting kan verkry word op die Nativa webwerf (www.nativa.co.za).