

SKEDULERINGSSTATUS: Sal toegeken word sodra geregistreer.

GEREGISTREERDE HANDELSNAAM (en doseringsvorm):

Sambucol Sagte Pastille

SAMESTELLING:

Elke **Sambucol** Pastil bevat:
Sambucus nigra (Black Elderberry) vrugtesap droë-ekstrak
Ekwivalent aan vars sap 1200 mg
Askorbiensuur (Vit C) 50 mg
Sink (as glukonaat) 3 mg
Heuning 100 mg

FARMAKOLOGIESE KLASSIFIKASIE:

Kategorie D Komplimentêre Medisyne

FARMAKOLOGIESE WERKING:

Verkoekvirusse kan nie self vermeerder nie. **Black Elderberry (Sambucus nigra)** se anti-virale werking het die vermoë om die eerste aanslag van die virus te help teen staan. Die virus moet aan die selwand van gesonde selle koppel, die selle indring om te kan voortbestaan en vermeerder en na ander selle versprei. Kliniese bewys om verkoeke simptome hok te slaan en herstel te versnel.

Sambucus Nigra aktiveer die gesonde immuunstelsel deur die verhoging van inflammasoriese sitokine produksie* Askorbiensuur (Vit C) speel 'n belangrike rol in immuunstelsel ondersteuning. Sink speel 'n belangrike rol in immuunstelsel ondersteuning Heuning het 'n smerende aksie.

Hierdie medisyne is nog nie deur die Medisynbeheerraad geëvalueer nie, en is nie bedoel om 'n diagnose te maak, 'n sieketoestand te behandel, te voorkom of om as kuur gebruik te word nie.

Indikasies:

Help om seer keel te verlig en immuunondersteuning.

***Produkspesifieke Kliniese Studies Met Black Elderberry (Sambucus nigra):**

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| Patients taking Sambucol - Symptoms were relieved on average 4 days earlier, and the use of rescue medication was significantly less than those compared to placebo. | A Randomized Study of the efficacy & Safety of Oral Black Elderberry Extract (Sambucol) in the treatment of Influenza A & B Virus Infections. Z Zakay Rones, E Thom, T Wolland & J Wadstein. The Journal of International Medical Research 2004;32: 132-140 |
| We conclude from this study, that in addition to its anti-viral properties, Sambucol activates the healthy immune system by increasing inflammatory cytokine production. | "The Effect of SAMBUCOL , a Black Elderberry-based, natural product, on the production of human cytokines: I. Inflammatory cytokines." V. Barak, T Halperin, I Kalickman - Oncology Dept Hadassah Medical Organization P.O.B. 12000 Jerusalem Israel. EUROPEAN Cytokine Network Volume 12, Number 2 290-6 June 2001 |

KONTRA-INDIKASIES:

Hipersensitiewiteit teenoor enige van die bestanddele.
Swangerskap en laktasie omdat veiligheid nog nie bo alle twyfel vasgestel is nie. Diabetis - Tipe 1 Diabetiese pasiënte moet hulle insulien aanpas volgens die hoeveelhede heuning. Tipe 2 Diabetiese pasiënte moet liewer die pastille vermy en die kapsules neem.

PASIËNTINLIGTING VOUBLIJET

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NEWE-EFFEKTE EN SPESIALE VOORSORGMATREËLS:

Geen bekende newe-effekte. Indien u enige newe-effekte of sensitiewiteit ervaar met die gebruik van **Sambucol** Pastille, kontak u dokter of apteker onmiddellik. Indien u simptome nie verbeter, kontak u dokter of apteker onmiddellik.

Vitamiene moet nie 'n gebalanseerde dieet vervang. Nie geskik vir kinders onder die ouderdom van 6 jaar.

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Die pastille bevat 7.1 g Malitol en 6.4 g Sorbitol in die maksimum aanbevele dosis wat 'n lakserende effek mag hê en ook diarree kan veroorsaak. Bevat suiker as deel van heuning.

Waarskuwing: Bevat Sink wat gevaarlik kan wees as hoë dosisse geneem word of oor 'n lang tydperk.

Uitwerking op die vermoë om te bestuur en masjinerie te gebruik:

Sambucol behoort nie die vermoë om te bestuur of die gebruik van masjinerie te beïnvloed nie. Dit is egter altyd raadsaam om bedagsaam te wees vir bogenoemde totdat u seker is daar is nie newe-effekte nie.

INTERAKSIES:

Geen interaksies bekend.

SWANGERSKAP EN LAKTASIE:

Die veiligheid met die neem van **Sambucol** Pastille tydens swangerskap en borsvoeding is nog nie bo al twyfel bewys nie.

DOSIS EN GEBRUIKSAANWYSINGS:

Volwasse: Suig 1-2 pastille elke uur soos nodig; Tot 8 pastille per dag.

Kinders 9-12 jr: Suig een pastil elke 1-2 ure; Tot 8 pastille per dag.

Kinders 6-9 jr: Suig een pastil elke 3 ure; Tot 4 pastille per dag.

Begin verkieslik binne 48-uur na simptome begin het. Of soos deur u dokter of apteker aanbeveel.

BEKENDE SIMPTOME VAN OORDOSERING EN DIE BEHANDELING DAARVAN:

Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:

Sagte Pers Ronde Pastille.

AANBIEDING:

Sambucol Pastille is beskikbaar in 'n stolpakkie van 20 pastille.

BERGINGSINSTRUKSIES:

Moet nie gebruik word indien die foelie gebreek is. Sodra oopgemaak hou dig versêel en moet geberg word in 'n droë omgewing onder 25 °C. Hou buite bereik van kinders.

REGISTRASIENOMMER:

Sal toegeken word.

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:

KCP Products cc,
Posbus 1072, Knysna 6570
Web adres: www.sambucol.com
epos: kcpinfo@mweb.co.za
Tel no: +27 (0) 44 382 0382

DATUM VAN PUBLISERING VAN HIERDIE VOUBLIJET:

17 Maart 2017

Pro-Print

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Tel no: +27 (0) 44 382 0382

Datum van publisering van hierdie voubljet

17 Maart 2017

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SCHEDULING STATUS: To be allocated once registered.

PROPRIETARY NAME (and dosage form):

Sambucol Soft Pastilles

COMPOSITION:

Sambucus nigra (Black Elderberry) fruit juice dry pdr 6:1 200 mg
Equivalent to fresh juice 1200mg
Ascorbic Acid (Vit C) 50mg
Zinc (As Gluconate) 3mg
Honey 100mg

PHARMACOLOGICAL CLASSIFICATION:

Category D Western herbal complementary medicine

PHARMACOLOGICAL ACTION:

A flu virus is unable to replicate on its own.

Sambucus nigra's (Black Elderberry) antiviral action has demonstrated the ability to help fight the first invasion of the virus.

It must fuse to and invade other healthy cells to be able to grow and multiply, and spread to other cells. **Black Elderberry** can help reduce the fusion of the virus to healthy cells and its ability to multiply and spread. Clinically trialled to help fight the flu symptoms and speed recovery*.

Sambucus Nigra activates the healthy immune system by increasing inflammatory cytokine production*

Ascorbic Acid (Vit C) & Zinc plays an important role in maintaining proper immune function. Honey has lubricating properties.

This medicine has not yet been evaluated by the Medicines Control Council and is not intended to diagnose, treat, cure or prevent any disease.

INDICATIONS:

To help soothe sore throat, immune system support.

***Product Specific Clinical Trials with Black Elderberry Sambucus nigra:**

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CONTRAINDICATIONS:

Hypersensitivity to any of the ingredients.

Pregnancy or lactation as safety has not been established. Diabetes - Type 1 Diabetic patients should adjust their insulin according to the honey in the dosage. Type 2 Diabetic patients should avoid **Sambucol** Pastilles and choose to take the capsules instead.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

No known side effects have been reported. If you experience any side

effects or sensitivity towards **Sambucol** pastilles contact your doctor or pharmacist immediately.

If symptoms persists contact your doctor or pharmacist immediately. Vitamins should not replace a balanced diet. Not suitable for children under the age of 6 years.

Lozenges contain 7.1 g of Malitol and 6.4 g of Sorbitol at the maximum recommended dose which might have a laxative effect and might cause diarrhoea. Contains sugar as part of honey.

Warning: Contains Zinc which might be dangerous if taken in large amounts.

Effects on ability to drive and use machines

Sambucol is not likely to impair your ability to drive vehicles or operate machinery. However do take care if you take **Sambucol** until you know how it will affect you.

INTERACTIONS:

No known interactions.

PREGNANCY AND LACTATION:

The safety of **Sambucol** during pregnancy and whilst breastfeeding has not been established.

DOSEAGE AND DIRECTIONS FOR USE:

Adults: Suck one to two pastilles every hour, or as needed; Up to 8 pastilles per day.

Children 9-12 yrs: Suck one pastille every 1-2 hours; Up to 8 per day.

Children 6-9 yrs: Suck one pastille every 3 hours; Up to 4 per day

Best taken at first sign of sore throat – within 48 hours of the onset of symptoms.

Or as recommended by your healthcare professional.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Treatment is symptomatic and supportive.

IDENTIFICATION:

Purple Round Soft Pastille.

PRESENTATION:

Do not use if blister has been broken. 20 Soft pastilles in blister sealed pack in an outer carton.

STORAGE INSTRUCTIONS:

Store at or below 25 °C in a cool dry place. Keep out of reach of children.

REFERENCE NUMBER:

To be allocated.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

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PATIENT INFORMATION LEAFLET

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17 March 2017



PRO-PRINT (PTY) LTD
THE PROFESSIONALS IN PRINT

REPRO

Date: 27th March 2017
Operator: Elizabeth Choudree
Customer: KCP Products cc
Product Name: Sambucol Soft Pastilles Leaflet
Product Code: --
Dimensions: 140 x 240 mm
Fold Size: 140 x 30 mm
Font Size: 6 point Helvetica Condensed
Colours: (1) Black

Barcode: --
Pharmacode: (Ref. 17) 1101
Stock: 50 gsm Aviator
Proof Status: 1st (First)

Proof read by:

Reset: Alterations: Disk/Possie:

No alterations – proceed as soon as possible

Note alterations – Further proof is required

PLEASE CHECK CAREFULLY.

Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.

Signature:.....Date:.....

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