

SKEDULERINGSSTATUS: Sal toegeken word sodra geregistreer.

Geregistreerde Handelsnaam (en doseringvorm):

Sambucol Cold & Flu Stroop

SAMESTELLING:

Elke 15ml bevat *Sambucus nigra* (Black Elderberry) Vrugtesap 5.7 gram

FARMAKOLOGIESE KLASSIFIKASIE:

Kategorie D Komplimentêre Medisyne

FARMAKOLOGIESE WERKING:

Verkouevirusse kan nie self vermeerder nie. **Sambucol** se antivirale werking het die vermoë om die eerste aanslag van die virus teen te 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. Klinies bewys om verkouesimptome hok te slaan en herstel te versnel. Verminder verkoue met die helfte en word tweekeer so gou gesond.

Hierdie medisyne is nog nie deur die Medisynebeheerraad ge-evalueer nie, en is nie bedoel om 'n diagnose te maak, 'n siektetoestand te behandel, te voorkom of om as kuur gebruik te word nie.

INDIKASIES:

Klinies bewys om die duur en graad van verkouesimptome met die helfte te verminder. Kongestie, Hoes, Ongemak en Pyn, Koors, en Seer Keel*.

Immuunsisteem Ondersteuning*.

***Produkspesifieke Kliniese studies gedoen met SAMBUCOL:**

Patients taking Sambucol - Symptoms were relieved on average 4 days earlier, and the use of rescue medication were 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. <i>The Journal of International Medical Research</i> 2004;32: 132-140
We conclude from this study, that in addition to its antiviral 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. <i>EUROPINE Cytokine Network Volume 12, Number 2 290-6 June 2001</i>

KONTRA-INDIKASIES:

Hipersensitiwiteit teenoor enige van die bestanddele. Swangerskap en laktasie omdat veiligheid nog nie bo alle twyfel vasgestel is nie. Diabetes - Tipe 1 Diabetiese pasiënte moet hulle insulien aanpas volgens die stroop dosis. Tipe 2 Diabetiese pasiënte moet die stroop vermy en liever die kapsules neem.

NEWE-EFFEKTE EN SPESIALE VOORSORGMATREËLS:

Geen bekende newe-effekte aangemeld nie. Indien u enige newe-

effekte of sensitiwiteit ervaar met die gebruik van **Sambucol**, kontak u dokter of apteker onmiddellik. Indien u simptome of hoes nie verbeter, kontak u dokter of apteker onmiddellik. Bevat kaliumsorbaat, glukose en gluten afkomstig van koring. Veiligheidsverseël: Moet nie gebruik indien die plastiekseël gebreek is. Geen bygevoegde laktose, gis, melkderivate of kunsmatige kleurstowwe.

Uitwerking om te bestuur:

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** tydens swangerskap en borsvoeding is nog nie bo all twyfel bewys nie.

DOSIS EN GEBRUIKSAANWYSINGS:

Volwassenes en Kinders: 15 ml 3-4 x daagliks.

Begin verkieslik binne 48-uur na simptome begin het.

Onderhoudsdosis: 15 ml een tot tweemaal per dag.

Kinders: 5-12 jr: 15 ml 2 x daagliks.

Onderhouds Dosis: 15 ml daagliks.

Kinders: 2-4 jr 7.5-15 ml eenmaal 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:

Dik vloeibare rooibrui stroop.

AANBIEDING:

120 ml

SAMBUCOL stroop is beskikbaar in 'n donkerbruin bottel met 'n prop. Die bottel is toegesluit met 'n plastiekseël en verpak in 'n karton.

BERGINGSINSTRUKSIES:

Sodra oopgemaak hou dig verseël en moet geberg word in 'n droë omgewing onder 25 °C. HOU BUITE DIE BEREIK VAN KINDERS.

REGISTRASIONOMMER:

Sal toegeken word.

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE

REGISTRASIESERTIFIKAAT:

KCP Products cc,

Posbus 1072, Knysna 6570 Suid Afrika

Web adres: www.sambucol.com

epos: kcpinfo@mweb.co.za

Tel. nr.: +27 (0) 44 382 0382

DATUM VAN PUBLISERING VAN HIERDIE VOUBILJET:

15 Mei 2014

Pro-Print



PASIËNTINLIGTING VOUBILJET

SKEDULERINGSSTATUS: Sal toegeken word sodra geregistreer.

Geregistreerde Handelsnaam (en doseringvorm):

Sambucol Cold & Flu Stroop

SAMESTELLING:

Elke 15ml bevat *Sambucus nigra* (Black Elderberry) Vrugtesap 5.7 gram

INDIKASIES:

Klinies bewys om die duur en graad van verkouesimptome met die helfte te verminder. Kongestie, Hoes, Ongemak en Pyn, Koors, en Seer Keel*.

Immuunsisteem Ondersteuning*.

***Produkspesifieke Kliniese studies gedoen met SAMBUCOL:**

Patients taking Sambucol - Symptoms were relieved on average 4 days earlier, and the use of rescue medication were 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. <i>The Journal of International Medical Research</i> 2004;32: 132-140
We conclude from this study, that in addition to its antiviral 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. <i>EUROPINE Cytokine Network Volume 12, Number 2 290-6 June 2001</i>

KONTRA-INDIKASIES:

Hipersensitiwiteit teenoor enige van die bestanddele. Swangerskap en laktasie omdat veiligheid nog nie bo alle twyfel vasgestel is nie. Diabetes - Tipe 1 Diabetiese pasiënte moet hulle insulien aanpas volgens die stroop dosis. Tipe 2 Diabetiese pasiënte moet die stroop vermy en liever die kapsules neem.

NEWE-EFFEKTE EN SPESIALE VOORSORGMATREËLS:

Geen bekende newe-effekte aangemeld nie. Indien u enige newe-effekte of sensitiwiteit ervaar met die gebruik van **Sambucol**, kontak u dokter of apteker onmiddellik. Indien u simptome of hoes nie verbeter, kontak u dokter of apteker onmiddellik. Bevat kaliumsorbaat, glukose en gluten afkomstig van koring.

Veiligheidsverseël: Moet nie gebruik indien die plastiekseël gebreek is. Geen bygevoegde laktose, gis, melkderivate of kunsmatige kleurstowwe.

Uitwerking om te bestuur:

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** tydens swangerskap en borsvoeding is nog nie bo all twyfel bewys nie.

DOSIS EN GEBRUIKSAANWYSINGS:

Volwassenes en Kinders: 15 ml 3-4 x daagliks.

Begin verkieslik binne 48-uur na simptome begin het.

Onderhoudsdosis: 15 ml een tot tweemaal per dag.

Kinders: 5-12 jr: 15 ml 2 x daagliks.

Onderhouds Dosis: 15 ml daagliks.

Kinders: 2-4 jr 7.5-15 ml eenmaal per dag.

Begin verkieslik binne 48-uur na simptome begin het.

Of soos deur u dokter of apteker aanbeveel.

IDENTIFIKASIE:

Dik vloeibare rooibrui stroop.

AANBIEDING:

120 ml

SAMBUCOL stroop is beskikbaar in 'n donkerbruin bottel met 'n skroef prop. Die bottel is toegesluit met 'n plastiekseël en verpak in 'n karton.

BERGINGSINSTRUKSIES:

Sodra oopgemaak hou dig verseël en moet geberg word in 'n droë omgewing onder 25 °C. HOU BUITE DIE BEREIK VAN KINDERS.

REGISTRASIONOMMER:

Sal toegeken word.

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE

REGISTRASIESERTIFIKAAT:

KCP Products cc,

Posbus 1072, Knysna 6570 Suid Afrika

Web adres: www.sambucol.com

epos: kcpinfo@mweb.co.za

Tel. nr.: +27 (0) 44 382 0382

DATUM VAN PUBLISERING VAN HIERDIE VOUBILJET:

15 Mei 2014

Pro-Print

SCHEDULING STATUS: To be allocated once registered.

PROPRIETARY NAME (and dosage form):

Sambucol Cold & Flu Syrup

COMPOSITION:

Each 15 ml Contains: **Sambucus nigra (Black Elderberry)** fruit juice 5.7 gram

PHARMACOLOGICAL CLASSIFICATION:

Category D Western herbal complementary medicine

PHARMACOLOGICAL ACTION:

A flu virus is unable to replicate on its own. **Sambucol's** anti-viral 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. **Sambucol** 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. Cut your flu in half so that you get better twice as fast. This medicine has not been evaluated by the Medicines Control Council and is not intended to diagnose, treat, cure or prevent any disease.

INDICATIONS:

Clinically trialled to help cut the duration and severity of flu symptoms by half*.

Congestion, Cough, Aches and Pains, Fever, Sore throat. Immune System Support*.

***Product Specific Clinical Trials Done with Sambucol:**

Patients taking Sambucol - Symptoms were relieved on average 4 days earlier, and the use of rescue medication were 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. EUROPINE Cytokine Network Volume 12, Number 2 290-6 June 2001
---	---

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 **Sambucol** Syrup dosage. Type 2 Diabetic patients should avoid **Sambucol** Syrup and choose to take the capsules instead.

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: To be allocated once registered.

PROPRIETARY NAME (and dosage form):

Sambucol Cold & Flu Syrup

COMPOSITION:

Each 15 ml Contains: **Sambucus nigra (Black Elderberry)** fruit juice 5.7 gram

INDICATIONS:

Clinically trialled to help cut the duration and severity of flu symptoms by half*.

Congestion, Cough, Aches and Pains, Fever, Sore throat. Immune System Support*.

***Product Specific Clinical Trials Done with Sambucol:**

Patients taking Sambucol - Symptoms were relieved on average 4 days earlier, and the use of rescue medication were 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. EUROPINE Cytokine Network Volume 12, Number 2 290-6 June 2001
---	---

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 **Sambucol** Syrup dosage. Type 2 Diabetic patients should avoid **Sambucol** Syrup 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** contact your doctor or pharmacist immediately. If symptoms or cough persists contact your doctor or pharmacist immediately.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

No known side effects have been reported. If you experience any side effects or sensitivity towards **Sambucol** contact your doctor or pharmacist immediately.

If symptoms or cough persists contact your doctor or pharmacist immediately.

Not to be used in children under 2 years of age without medical advice.

Contains potassium sorbate, glucose and gluten derived from wheat.

Do not use if tamper-evident seal is broken or missing.

No added: lactose, yeast, dairy or artificial colours.

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 & LACTATION:

The safety of **Sambucol** Cold & flu syrup during pregnancy and whilst breastfeeding has not been established.

DOSAGE AND DIRECTIONS FOR USE:

Adults: 15 ml 3-4 times daily.

Maintenance: 15 ml once to twice daily.

Children 5-12 yrs: 15 ml twice daily.

Maintenance: 15 ml daily.

Children 2-4 yrs: 7.5 - 15 ml once daily.

Best taken at first sign of cold and flu - within 48 hrs 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:

Thick reddish brown liquid.

PRESENTATION:

120 ml Amber bottles, with a cap with lift and peel induction seal in an inner carton.

STORAGE INSTRUCTIONS:

Store at or below 30 °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:

KCP Products cc
P.O. Box 1072
Knysna 6570 South Africa
Web address: www.sambucol.com
e-mail: kcpinfo@mweb.co.za
Tel. no.: +27 (0) 44 382 0382

DATE OF PUBLICATION OF THE PACKAGE INSERT:

15 May 2014

Not to be used in children under 2 years of age without medical advice.

Contains potassium sorbate, glucose and gluten derived from wheat.

Do not use if tamper-evident seal is broken or missing.

No added: lactose, yeast, dairy or artificial colours.

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 & LACTATION:

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

DOSAGE AND DIRECTIONS FOR USE:

Adults: 15 ml 3-4 times daily.

Maintenance: 15 ml once to twice daily.

Children 5-12 yrs: 15 ml twice daily.

Maintenance: 15 ml daily.

Children 2-4 yrs: 7.5 - 15 ml once daily.

Best taken at first sign of cold and flu - within 48 hrs of the onset of symptoms.

Or as recommended by your healthcare professional.

IDENTIFICATION:

Thick reddish brown liquid.

PRESENTATION:

120 ml Amber bottles, with a cap with lift and peel induction seal in an inner carton.

STORAGE INSTRUCTIONS:

Store at or below 30 °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:

KCP Products cc
P.O. Box 1072
Knysna 6570 South Africa
Web address: www.sambucol.com
e-mail: kcpinfo@mweb.co.za
Tel. no.: +27 (0) 44 382 0382

DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

15 May 2014



PRO-PRINT (PTY) LTD
THE PROFESSIONALS IN PRINT

REPRO

Date: 14th February 2017
Operator: Elizabeth Choudree
Customer: KCP Products cc
Product Name: Sambucol Cold & Flu Syrup Leaflet
Product Code: --
Dimensions: 126 x 265 mm
Fold Size: 126 x 34 mm
Font Size: 6 point Helvetica Condensed
Colours: (1) Black
--
Barcode: --
Pharmacode: (Ref. 11) 011
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:**.....

PROOF NOT READ – NO COPY SUPPLIED