

SCHEDULING STATUS: **S0**

Sambucol®

BLACK ELDERBERRY

KIDS GUMMIES

Each Gummy contains *Sambucus nigra* (Elderberry Juice) 35 mg
Contains sugar.

- Complementary medicine Category D – Combination Product
- This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

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

SAMBUCOL KIDS is available without a doctor's prescription, for you to maintain your health. Never the less you still need to use SAMBUCOL KIDS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share SAMBUCOL KIDS with any other person.
- Ask your pharmacist if you need more information or advice.

WHAT IS IN THIS LEAFLET:

1. What SAMBUCOL KIDS is and what it is used for
2. What you need to know before you take SAMBUCOL KIDS
3. How to take SAMBUCOL KIDS
4. Possible side effects
5. How to store SAMBUCOL KIDS
6. Contents of the pack and other information

1. WHAT SAMBUCOL KIDS IS AND WHAT IT IS USED FOR:

Sambucus nigra has been used to help relieve the symptoms of colds and flu and to help relieve nasal congestion associated with sinusitis and hay fever. *Sambucus nigra* is commonly used as an antioxidant that helps protect cells and reduce the oxidative effect of oxidative cell damage caused by free radicals.

SAMBUCOL KIDS gummies contains Black Elderberry plus Vitamin C which contributes to the normal function of the immune system.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SAMBUCOL KIDS:

Do not take SAMBUCOL KIDS:

- If you are allergic (hypersensitive) to *Sambucus nigra* (Black Elderberry) or any other ingredients of SAMBUCOL KIDS (listed in section 6).

Warnings and precautions:

Take special care with SAMBUCOL KIDS:

Do not exceed the recommended dose.

Contains sugar which may have an effect on the glycaemic control of patients with diabetes mellitus.

Children and adolescents:

SAMBUCOL KIDS is not intended for use in children under the age of 4 years old.

Other medicines and SAMBUCOL KIDS:

Be watchful when taking Elderberry with Cytochrome P450 3A4 (CYP3A4) substrates.

Be cautious with the combination of Elderberry & Immunosuppressants.

Elderberry seems to stimulate production of cytokines including interleukin and tumor necrosis factor.

Theoretically, elderberry might exacerbate autoimmune disease by stimulating disease activity. Advise patients with autoimmune diseases such as multiple sclerosis, systemic lupus erythematosus (SLE), rheumatoid arthritis (RA), or others to avoid taking elderberry.

Always tell your healthcare professional if you are taking any other medicine.

Pregnancy and Breastfeeding:

Safety during pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or health care provider for advice before taking this medicine.

3. HOW TO TAKE SAMBUCOL KIDS:

Do not share medicines prescribed for you with any other person.

Always take SAMBUCOL KIDS exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

SAMBUCOL KIDS can be used throughout the year to support your child's immune system, especially during school terms and winter season.

Do not swallow whole.

RECOMMENDED DAILY DOSE:

CHILDREN 4-12 YEARS: Chew 2 gummies daily

INCREASED DOSE FOR EXTRA SUPPORT:

CHILDREN 4-12 YEARS: Chew 2 gummies twice daily

4. POSSIBLE SIDE EFFECTS:

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

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

Reporting of suspected adverse reactions

If you get side effects, talk to your pharmacist. 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 SAMBUCOL KIDS.

5. HOW TO STORE SAMBUCOL KIDS:

Store all medicines out of reach of children.

- Store in a dry place below 25°C.
- Store in the original container.
- Do not use after the expiry date stated on the container.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What SAMBUCOL KIDS contains:

- The active substances are:

Sambucus nigra (Black Elderberry) 30 mg [(DER 32:1) equivalent to 1.2 g elderberry fruit]

Ascorbic acid (vitamin C) 30 mg

The other ingredients are Glucose syrup, Sugar, Dextrose, Gelling

Agent: Pectin, Vitamin C (L-Ascorbic Acid), Black Elderberry (*Sambucus nigra*) Extract, Vegetable Oils (Coconut, Palm), Raspberry Flavouring, Acidity Regulators: Sodium Citrates, Citric Acid; Glazing Agent: Carnauba Wax. No added: yeast, dairy or artificial colours.

What SAMBUCOL KIDS looks like and contents of the pack
SAMBUCOL KIDS is a berry flavoured gummie in pack size of 30 gummies.

Holder of Certificate of Registration

SFI South Africa (Pty) Ltd
121 Mitchell Street
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The leaflet was last revised in

March 2023.

Application number:

To be allocated.

Access to the corresponding Professional information:

Visit www.flordis.co.za

SKEDULERINGSSTATUS: **S0**

Sambucol®

BLACK ELDERBERRY

KIDS GUMMIES

Elke Gummy bevat *Sambucus nigra* (Elderberry Juice) 35 mg
Bevat suiker.

- Komplementêre Middels Kategorie D – Kombinasie Produk
- Hierdie ongeregistreerde medisyne is nie deur SAHPRA vir kwaliteit, veiligheid en sy bedoelde gebruik geëvalueer nie

Lees asseblief hierdie inligtingsblaadjie in sy geheel sorgvuldig deur, aangesien dit belangrike inligting vir jou bevat.

SAMBUCOL KIDS is sonder 'n doktersvoorskrif beskikbaar, sodat jy 'n ligte siekte kan behandel. Jy moet nogtans, ten einde die beste resultate daaruit te verkry SAMBUCOL KIDS versigtig gebruik.

- Hou hierdie blaadjie. Jy sal dit dalk weer wil deurlees.
- Moenie SAMBUCOL KIDS met enige ander persoon deel nie.
- Vra jou apteker indien jy verdere inligting of raad nodig het.

WAT IS IN HIERDIE BLAADJIE:

1. Waarvoor is SAMBUCOL KIDS en waarvoor word dit gebruik.
2. Wat u moet weet voordat jy SAMBUCOL KIDS neem.
3. Hoe om SAMBUCOL KIDS te neem.
4. Moontlike nuwe-effekte.
5. Hoe om SAMBUCOL KIDS te bewaar.
6. Inhoud van die verpakking en ander inligting.

1. WAARVOOR IS SAMBUCOL KIDS EN WAARVOOR WORD DIT GEBRUIK:

Sambucus nigra word gebruik om die simptome van verkoue en griep te help verlig en om neusverstopping wat verband hou met sinusitis en hooikoors te help verlig. *Sambucus nigra* word ook algemeen gebruik as 'n antioksidant wat help om selle te beskerm teen die oksidatiewe effek van oksidatiewe selskade wat deur vrye radikale veroorsaak word, te verminder. SAMBUCOL KIDS GUMMIES bevat Black Elderberry plus Vitamien C wat bydra tot die normale funksie van die immuunstelsel.

2. WAT JY MOET WEET VOORDAT JY SAMBUCOL KIDS NEEM Moenie SAMBUCOL KIDS gebruik:

- As jy hipersensitief (allergies) teenoor *Sambucus nigra* (Black Elderberry) of enige van die ander bestanddele van SAMBUCOL KIDS is nie (gelys in afdeling 6).

Waarskuwings en voorsorgmaatreëls:

Wees veral versigtig met SAMBUCOL KIDS:
Moenie die aanbevele dosis oorskry nie.
Bevat suiker wat 'n effek kan hê op die glukemiese beheer van pasiënte met diabetes mellitus.

Kinders en adolessente:

SAMBUCOL KIDS is nie bedoel vir gebruik by kinders onder die ouderdom van 4 jaar oud nie.

Ander medisyne en SAMBUCOL KIDS:

Wees versigtig wanneer Elderberry met Cytochrome P450 3 A4 (CYP3A4) substrate geneem word.

Wees versigtig met die kombinasie van Elderberry en immuunonderdrukkers.

Elderberry stimuleer die produksie van sitokiene, insluitend interleukien en tumornekrosefaktor.

Teoreties kan Elderberry outo-immuunsiekte vererger deur siekteaktiwiteit te stimuleer. Adviseer pasiënte met outo-immuun siektes soos veelvuldige sklerose, sistemiese lupus erythematosus (SLE), rumatoïede artritis (RA), of ander om Elderberry te vermy.

Vertel altyd jou gesondheidswerker as jy enige ander medisyne gebruik.

Swangerskap en borsvoed:

Veiligheid tydens swangerskap en borsvoed is nie vasgestel nie. As jy swanger is of borsvoed, dink jy is dalk swanger of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of gesondheidswerker vir advies voordat jy hierdie medisyne gebruik.

3. HOE OM SAMBUCOL KIDS TE NEEM:

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem SAMBUCOL KIDS altyd presies soos jou dokter of apteker opdrag gegee het. Jy moet seker maak met jou dokter of apteker as jy onseker is nie.

SAMBUCOL KIDS kan gebruik word deur die jaar om jou kind se immuunstelsel te ondersteun, veral gedurende skoolkwartale en winterseisoen.

Moenie heel sluk nie.

AANBEVELE DAAGLIKSE DOSIS:

KINDERS 4-12 JAAR: Kou daaglik 2 gummies

VERHOOGDE DOSIS VIR EKSTRA ONDERSTEUNING:

KINDERS 4-12 JAAR: Kou 2 gummies twee keer per dag

4. MOONTLIKE NUWE-EFFEKTE:

Geen bekende nuwe-effekte is aangemeld nie. As u enige nuwe-effekte of sensitiwiteit teenoor SAMBUCOL KIDServaar, kontak jou dokter of apteker onmiddellik.

As simptome of hoes voortduur, kontak jou dokter of apteker onmiddellik.

Rapportering van nuwe-effekte

As jy nuwe-effekte kry, praat met jou apteker. Jy kan ook nuwe-effekte aan SAHPRA rapporteer via die "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind word onder SAHPRA se publikasies:

<https://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van SAMBUCOL KIDS te verskaf.

5. HOE OM SAMBUCOL KIDS TE BEWAAR:

Bewaar alle medisyne buite die bereik van kinders.

- Berg in 'n droë plek onder 25°C.
 - Berg in die oorspronklike verpakking/houer.
 - Moet nie gebruik na die vervaldatum soos op die houder nie.
- Besorg alle ongebruikte medisyne aan jou apteker.
Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. Toilette) weggooi nie.

6. INHOUD VAN DIE VERPAKKING EN ANDER INLIGTING: Wat SAMBUCOL KIDS bevat:

- Die aktiewe bestanddeel is:

Sambucus nigra (Swart Vlierbessie) 30 mg [(DER 32:1) gelykstaande aan 1,2 g vlierbessie vrugte]

Askorbienzuur (vitamien C) 30 mg

Die ander bestanddele is Glukosestroop, Suiker, Dekstrose, Geling

Middel: Pektien, Vitamien C (L-askorbienzuur), Swart Vlierbessie (*Sambucus nigra*) uittreksel, Groente-olies (klapper, palm), Framboosgeursel, Suurreguleerders: Natriumsitraat, Sitroensuur; Glasmiddel: Carnauba-was. Geen bygevoegde nie: gis, suiwel of kunsmatige kleure nie.

Hoe SAMBUCOL KIDS lyk en die inhoud van die verpakking
SAMBUCOL KIDS is 'n bessie-gegeurde gummie in pakgrootte van 30 gummies.

Houer van die Registrasiesertifikaat

SFI Suid-Afrika (Edms.) Bpk

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Die blaadjie is laas hersien in:

Maart 2023.

Aansoeknommer:

Moet nog toegeken word.

Toegang tot die toepaslike professionele inligting:

Besoek www.flordis.co.za