

SCHEDULING STATUS: **S0**

Sambucol®

BLACK ELDERBERRY

IMMUNO FORTE EFFERVESCENT TABLETS

Each effervescent tablet contains *Sambucus nigra* (Elderberry Juice) 154 mg
Contains sugar: Sweetener

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

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

WHAT IS IN THIS LEAFLET:

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

1. WHAT SAMBUCOL IMMUNO FORTE 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 hayfever. *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 Immuno Forte effervescent contains Black Elderberry plus Zinc and Vitamin C which contributes to the normal function of the immune system.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SAMBUCOL IMMUNO FORTE:

Do not take SAMBUCOL IMMUNO FORTE:

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

Warnings and precautions:

Take special care with SAMBUCOL IMMUNO FORTE:
Do not exceed the recommended dose.

Children and adolescents:

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

Other medicines and SAMBUCOL IMMUNO FORTE:

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.

Driving and using machines:

It is not always possible to predict to what extent SAMBUOL IMMUNO FORTE may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which SAMBUCOL IMMUNO FORTE affects them.

3. HOW TO TAKE SAMBUCOL IMMUNO FORTE:

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

Always take SAMBUCOL IMMUNO FORTE 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. Shake well before use. SAMBUCOL IMMUNO FORTE can be used throughout the year when needed.

Dissolve 1 tablet in a glass of cold or hot (not boiling) water (200ml).

RECOMMENDED DAILY DOSE:

ADULTS and CHILDREN over 12 years of age:

1 to 3 tablets daily

CHILDREN from 4 to 12 years old: 1 tablet daily

4. POSSIBLE SIDE EFFECTS:

No known side effects have been reported. If you experience any side effects or sensitivity towards SAMBUCOL IMMUNO FORTE 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 IMMUNO FORTE.

5. HOW TO STORE SAMBUCOL IMMUNO FORTE:

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 IMMUNO FORTE contains:

- The active substances are:

Sambucus nigra (Black Elderberry) 2.3 mg [Fruit, (DER 32:1)]
Ascorbic acid (vitamin C) 60 mg

Zinc (from zinc oxide) 7.5 mg

The other ingredients are Acidity regulators: Citric acid, Sodium Carbonate; Maltodextrin, Bulking agent: Sorbitol, Colour: Beetroot Red, Vitamin C (L-Ascorbic Acid), Zinc Sulfate, Black Elderberry (*Sambucus nigra*) Extract (DER 32:1),

Flavourings: Raspberry, Strawberry; Sweetener: Sucralose, Stabiliser: Polyvinylpyrrolidone. No added: yeast, dairy or artificial colours.

What SAMBUCOL IMMUNO FORTE looks like and contents of the pack

SAMBUCOL IMMUNO FORTE is a berry flavoured effervescent tablet in pack size of 15 effervescent tablets.

Holder of Certificate of Registration

SFI South Africa (Pty) Ltd
121 Mitchell Street
George, 6529
Tel: +27 (44) 874 2927

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

IMMUNO FORTE BRUISTABLETTE

Elke bruistablette bevat *Sambucus nigra* (Elderberry Juice) 154 mg
Bevat: Versoeter.

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

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

WAT IS IN HIERDIE BLAADJIE:

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

1. WAARVOOR IS SAMBUCOL IMMUNO FORTE 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 Immuno Forte bruistablette bevat Black Elderberry plus Sink en Vitamien C wat bydra tot die normale funksie van die immuunstelsel.

2. WAT JY MOET WEET VOORDAT JY SAMBUCOL IMMUNO FORTE NEEM

Moenie SAMBUCOL IMMUNO FORTE gebruik:

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

Waarskuwings en voorsorgmaatreëls:

Wees veral versigtig met SAMBUCOL IMMUNO FORTE:
Moenie die aanbevele dosis oorskry nie.

Kinders en adolessente:

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

Ander medisyne en SAMBUCOL IMMUNO FORTE:

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.

Bestuur en gebruik van masjiene:

Dit is nie altyd moontlik om te voorspel tot watter mate SAMBUOL IMMUNO FORTE met die daaglikse aktiwiteite van 'n pasiënt kan inmeng nie. Pasiënte moet verseker dat hulle nie by die bogenoemde aktiwiteite betrokke raak nie totdat hulle bewus is van die mate waarin SAMBUCOL IMMUNO FORTE hulle affekteer.

3. HOE OM SAMBUCOL IMMUNO FORTE TE NEEM:

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

Neem SAMBUCOL IMMUNO FORTE 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 IMMUNO FORTE kan deur die jaar gebruik word wanneer nodig.

Los 1 tablet op in 'n glas koue of warm (nie-kokende) water (200ml).

AANBEVOLE DAAGLIKSE DOSIS:

VOLWASSENES en KINDERS ouer as 12 jaar:

1 tot 3 tablette daaglik

KINDERS van 4 tot 12 jaar oud: 1 tablet daaglik

4. MOONTLIKE NUWE-EFFEKTE:

Geen bekende nuwe-effekte is aangemeld nie. As u enige nuwe-effekte of sensitiwiteit teenoor SAMBUCOL IMMUNO FORTE ervaar, 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 IMMUNO FORTE te verskaf.

5. HOE OM SAMBUCOL IMMUNO FORTE 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 houer 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 IMMUNO FORTE bevat:

- Die aktiewe bestanddeel is:

Sambucus nigra (Swart Vlierbessie) 2,3 mg [Vrugte, (DER 32:1)]

Askorbiensuur (vitamien C) 60 mg

Sink (van sinkoksied) 7,5 mg

Die ander bestanddele is: suurreguleerders: sitroensuur, natrium Karbonaat; Maltodekstrien, vulmiddel: sorbitol, kleur: Beetroot, vitamien C (L-askorbiensuur), sinksulfaat, Swart vlierbessie (*Sambucus nigra*) uittreksel (DER 32:1), Geurmiddels: Framboos, Aarbe; Versoeter: Sukralose, Stabiliseerder: Polivinilpirrolidon. Geen bygevoeg nie: gis, suiwel of kunsmatige kleure nie.

Hoe SAMBUCOL IMMUNO FORTE lyk en die inhoud van die verpakking

SAMBUCOL IMMUNO FORTE is 'n bessie-gegeurde bruistablet in pakgrootte van 15 bruistablette.

Houer van die Registrasiesertifikaat

SFI Suid-Afrika (Edms.) Bpk

Mitchellstraat 121

George, 6529

Tel: +27 (44) 874 2927

Die blaadtjie is laas hersien in:

Maart 2023.

Aansoeknommer:

Moet nog toegeken word.

Toegang tot die toepaslike professionele inligting:

Besoek www.flordis.co.za