

## PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Discipline specific

33.7 Combination Product

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

### SULFORACLEAR<sup>®</sup>, 60 Capsules

#### COMPOSITION

Each one (1) capsule of SULFORACLEAR<sup>®</sup> contains the following actives:

Broccoli (Brassica oleracea var. italica) [80% Sprout and 20% Floret Powder (myrosinase activity 30 mg glucose/g) providing 1 mg sulforaphane potential from 2 mg glucoraphanin]	204 mg
Calcium (as dicalcium phosphate)	80 mg
Broccoli (Brassica oleracea var. italica) [Seed 10:1 Extract providing glucoraphanin (10 mg)]	78,5 mg
Phosphorus (as dicalcium phosphate)	60 mg

**Inactive Ingredients:** Capsule (hydroxypropyl-methylcellulose), magnesium stearate (vegetable), microcrystalline cellulose, silica and stearic acid (vegetable).

**This product is suitable for Vegetarians, non-GMO, gluten & dairy free (Sugar Free)**

#### PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

#### INDICATION & PHARMACOLOGICAL ACTION

**SULFORACLEAR<sup>®</sup>** features ingredients that help support sulforaphane production. Sulforaphane is an activator of the body's own antioxidant and detoxifying enzymes and is responsible for the health benefits associated with broccoli consumption.

Ingredient	Uses for Ingredient
Broccoli (Brassica oleracea var. italica)	Supports detoxification, antioxidant activity, and may promote healthy liver function due to sulforaphane content.
Calcium (as dicalcium phosphate)	Essential for bone health, muscle function, and maintaining proper nerve transmission.
Broccoli (Brassica oleracea var. italica)	Provides glucoraphanin, which may support antioxidant activity and promote detoxification through sulforaphane production.
Phosphorus (as dicalcium phosphate)	Supports healthy bone and teeth formation, and plays a key role in energy production and cellular function.

#### CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take **SULFORACLEAR<sup>®</sup>** if you are hypersensitive (allergic) to any of the ingredients. If you have allergies, be sure to check with your healthcare professional before taking this supplement. **Antibiotics:** The active ingredients in **SULFORACLEAR<sup>®</sup>** may interact with antibiotics, take your antibiotics 2 hours before or after taking **SULFORACLEAR<sup>®</sup>**.

#### INTERACTIONS

Always tell your healthcare professional if you are taking any other medicine. It is possible that exposure of certain supplement ingredients may interfere with certain medications. (See Warnings & Special precautions)

#### DOSE AND DIRECTIONS FOR USE

**Adults:** Take 1 to 2 capsules daily or as directed by your healthcare practitioner. Do not take more than the recommended dose.



#### KNOWN SYMPTOMS OF OVER DOSAGE AND PARTICULARS OF ITS TREATMENT

See side-effects. **Treatment:** Discontinue use and consult your doctor, pharmacist or other healthcare professional for advice.

#### WARNING AND SPECIAL PRECAUTIONS

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: Individuals with thyroid issues (goitrogenic properties may interfere with iodine absorption), Hypercalcemia or kidney stones, Individuals with severe renal impairment or those on medications that affect calcium metabolism, Individuals with hyperphosphatemia or kidney disease. If you are taking the following medication, please consult with your healthcare professional before taking: May interact with thyroid medication (e.g., levothyroxine) due to its goitrogenic effects, medications metabolized by the liver (e.g., cytochrome P450 enzyme inhibitors), interfere with the absorption of certain medications such as antibiotics (e.g., tetracyclines, fluoroquinolones). May reduce the effectiveness of bisphosphonates (e.g., alendronate). May interfere with the absorption of calcium supplements or other minerals like iron and zinc. If any of the following happens, stop using **SULFORACLEAR<sup>®</sup>** and tell your doctor or go to the casualty department at your nearest hospital:

- Allergic reactions— rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing;
- These are all very serious effects. If you have them, you may have had a serious reaction to **SULFORACLEAR<sup>®</sup>**. You may need urgent medical attention or hospitalisation.

Side effects that usually do not require medical attention (report to your healthcare professional if they continue):

- nausea/vomiting, Mild gastrointestinal symptoms (e.g., indigestion, flatulence).

These are all very serious effects. If you have them, you may have had a serious reaction to **SULFORACLEAR<sup>®</sup>**. You may need urgent medical attention or hospitalisation. Seek advice from a healthcare professional if you have any medical condition. Discontinue use immediately should any adverse reaction occur. Read this leaflet carefully because it contains important information for you. This product is available without a doctor's prescription.

- Keep this leaflet. You may need to read it again.
  - Do not share medication with any other person.
  - Ask your pharmacist if you need more information or advice.
  - You must consult a doctor should your condition worsen or does not improve.
- DO NOT USE THIS PRODUCT:**
- If you are hypersensitive (allergic) to any of the ingredients listed.
  - Do not accept this package if seals are broken.

#### STORAGE INSTRUCTION

Store in a cool, dark place, below 25 °C.

Protect from direct sunlight and heat.

Store in the original bottle.

Keep the bottle tightly closed.

Replace the protective cap after each use.

Do not use after the expiry date stated on the bottle.

Do not use **SULFORACLEAR<sup>®</sup>** if you notice visible signs of deterioration.

#### IDENTIFICATION

Clear vegetable capsule with a light green fill.

#### PRESENTATION

A white 175 ml HDPE bottle with a white cap, induction seal, tamper shrink seal, wadding and silica gel sachet.

#### SIDE EFFECTS

Should your general health worsen, or if you experience any untoward effects while being exposed to this product, please consult your doctor, pharmacist or other healthcare professional for advice.

#### REGISTRATION NUMBER

To be allocated by SAHPRA upon registration.

This medicine has not been evaluated by SAHPRA for quality, safety, or intended use.

#### NAME AND BUSINESS ADDRESS OF APPLICANT

Distributed by:

Amipro Advanced Development Products (Pty) Ltd  
Unit 3, Eastgate Business Park, 1 South Road, Eastgate Extension,  
Sandton, 2146, Tel: 011-802-8101

#### DATE OF PUBLICATION

To be allocated by the regulatory authority.

# PROFESIONELE INLIGTINGSBLAD

SKEDULERINGSSTATUS: S0

Kategorie D: Komplementêre medisyne.

Dissipline: Dissipline spesifiek

33.7 Kombinasie produk

HANDELSNAAM EN DOSEERVORM,

## SULFORACLEAR® , 60 Kapsules

### SAMESTELING

Elke een (1) kapsules SULFORACLEAR® bevat die volgende aktiewe stowwe:

Broccoli (Brassica oleracea var. italica) [80% spruit en 20% floretpoeiër (myrosinase-aktiwiteit 30 mg glukose / g) wat 1 mg sulforafaanpotensiaal van 2 mg glucoraphanin bied]	204 mg
Kalsium (as dikalsiumfosfaat)	80 mg
Broccoli (Brassica oleracea var. italica) [Saad 10:1 Uittreksel wat glukorafanien verskaf (10 mg)]	78,5 mg
Fosfor (as dikalsiumfosfaat)	60 mg

**Onaktiewe bestanddele:** Kapsule (hidroksiopropyl-metielcellulose), magnesiumstearaat (groente), mikrokristallyne sellulose, silika en steariensuur (groente).

**Hierdie produk is geskik vir vegetariërs, nie-GGO, gluten- en suiwelvry (suikervry)**

### FARMAKOLOGIESE KLASSIFIKASIE

Komplementêre medisyne

### AANDUIDING EN FARMAKOLOGIESE WERKING

**SULFORACLEAR®** bevat bestanddele wat help om sulforafaan te ondersteun. Sulforafaan is 'n akteerder van die liggaam se eie antioksidante en ontgiftende ensieme en is verantwoordelik vir die gesondheidsvoordele verbonde aan broccoli-verbruik.

### INTERAKSIE

Vertel altyd jou gesondheidsorgpraktisyn as jy enige ander medisyne gebruik. Dit is moontlik dat blootstelling van sekere aanvullingsbestanddele met sekere medisyne 'n interaksie mag hê. (Sien **Waarskuwings** en **Spesiale voorsorgmaatreëls**)

### DOOSIS EN AANWYSINGS VIR GEBRUIK

**Volwassenes:** Neem daaglik 1 tot 2 kapsules of soos voorgeskryf deur jou gesondheidspraktisyn.

**Moenie meer as die aanbevole dosis neem nie.**

Bestanddeel	Gebruik vir bestanddeel
Broccoli (Brassica oleracea var. italica)	Ondersteun ontgifting, antioksidante aktiwiteit, en kan gesonde lewerfunksie bevorder as gevolg van sulforafaaninhoud.
Kalsium (as dikalsiumfosfaat)	Noodsaaklik vir beengesondheid, spierfunksie en die handhawing van behoorlike senuwee-oordrag.
Broccoli (Brassica oleracea var. italica)	Verskaf glucoraphanin, wat antioksidantaktiwiteit kan ondersteun en ontgifting deur sulforafaanproduksie kan bevorder.
Fosfor (as dikalsiumfosfaat)	Ondersteun gesonde been- en tandevorming, en speel 'n sleutelrol in energieproduksie en sellulêre funksie.

### KONTRA-INDIKASIE:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **SULFORACLEAR®** neem as jy hipersensitief (allergies) is vir enige van die bestanddele nie. As jy allergieë het, maak seker dat jy met jou gesondheidsorgpraktisyn gaan voordat jy hierdie aanvulling neem. **Antibiotika:** Die aktiewe bestanddele in **SULFORACLEAR®** kan interaksie hê met antibiotika, neem jou antibiotika 2 ure voor of na die neem van **SULFORACLEAR®**.

### WAARSKUWING EN SPESIALE VOORSORGMATREËLS

Indien jy enige van die volgende gedagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Individue met skildklierprobleme (goitrogene eienskappe kan inmeng met jodiumabsorpsie), Hiperkalsemie of nierstene, Individue met ernstige nierinkorting of dienege op medikasie wat kalsiummetabolisme beïnvloed, Individue met hiperfosfatemie of niersekte. As jy die volgende medikasie neem, raadpleeg asseblief jou gesondheidswerker voordat jy neem: Kan interaksie hê met skildklier medisyne (bv. levotiroksien) as gevolg van die goitrogene effekte daarvan, medisyne wat deur die lewer gemetaboliseer word (bv. sitochroom P450-ensiem-inhibeërs), inmeng met die absorpsie van sekere medisyne soos antibiotika (bv. alendronaat), Kan inmeng met die opname van kalsiumaanvullings of ander minerale soos yster en sink. As enige van die volgende gebeur, hou op om **SULFORACLEAR®** te gebruik en vertel jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- Allergiese reaksies- uitslag, jeuk / swelling (veral van die gesig / tong / keel), erge duiseligheid, probleme met asemhaling;
- Dit is alles baie ernstige gevolge. As u dit het, het jy dalk 'n ernstige reaksie op **SULFORACLEAR®** gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê. Nuwe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteur aan jou gesondheidsorgpraktisyn as hulle voortduur):
- naarheid / braking, Ligte gastro-intestinale simptome (bv. spysvertering, winderigheid).

Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op **SULFORACLEAR®** gehad. Miskien het u dringende mediese hulp of hospitalisasie nodig.

Raadpleeg 'n gesondheidsorgpraktisyn as u enige mediese toestand het. Staak gebruik onmiddellik indien enige nadelige reaksie plaasvind. Lees hierdie inligtingsblad aandagtig deur, want dit bevat belangrike inligting vir u. Hierdie produk is beskikbaar sonder doktersvoorskrif.

- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
  - Moenie medisyne met enige ander persoon deel nie.
  - Vra jou apteker of jy meer inligting of advies benodig.
  - Jy moet 'n dokter raadpleeg indien jou toestand vererger of nie verbeter nie.
- MOENIE HIERDIE PRODUK GEBRUIK NIE:**
- As jy hipersensitief (allergies) is vir enige van die bestanddele wat gelys word.
  - Jy moet nie hierdie produk aanvaar as seëls gebreek word nie.

### NEWE-EFFEKTE

Indien jou algemene gesondheid vererger of as jy enige nadelige effekte ervaar tydens die gebruik van hierdie medisyne, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgpraktisyn vir raad. As jy enige nuwe-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisyn in kennis.

### BEKENDE SIMPTOME VAN OORDOOSING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN

Sien nuwe-effekte.

**Behandeling:** Staak gebruik en raadpleeg jou dokter, apteker of ander gesondheidsorgpraktisyn vir advies.

### BERGING INSTRUKSIE

Bêre in 'n koel, donker plek, onder 25 °C.

Beskermt teen direkte sonlig en hitte.

Bêre n die oorspronklike bottel.

Hou die bottel styf toe.

Vervang die beskermdende dop na elke gebruik.

Moet nie gebruik word na die vervaldatum wat op die bottel aangedui word nie. Moenie **SULFORACLEAR®** gebruik as u sigbare tekens van agteruitgang opmerk nie.

### IDENTIFIKASIE

Duidelik groentekapsule met 'n liggroen vuisel.

### AANBIEDING

'n Wit 175 ml HDPE-bottel met 'n wit dop, induksieseël, peuterkrimpseël, spons en silikagelsakke.

### REGISTRASIE NOMMER

Om by registrasie deur SAHPRA toegeken te word.

Hierdie medisyne is nie deur SAHPRA geëvalueer vir kwaliteit, veiligheid of beoogde gebruik nie.

### NAAM EN BESIGHEIDSADRES VAN APPLIKANT

#### Versprei deur:

Amipro Advanced Development Products (Pty) Ltd  
Unit 3, Eastgate Business Park, 1 South Road,  
Eastgate Extension, Sandton, 2146, Tel: 011- 802-8101

### DATUM VAN PUBLIKASIE

Om deur die regulerende owerheid toegeken te word.