

## PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Health Supplement

33.12 Multiple Substance Formulation

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

### IMMUNE ACTIVE™, 60 Capsules

#### COMPOSITION

Each one (1) capsule of IMMUNE ACTIVE™ contain the following actives:

L-Cysteine (as N-acetyl-L-cysteine)	300 mg
Decaffeinated Green Tea (Camellia sinensis)	187,50 mg
[Leaf Extract standardized to 60 % (112,50 mg) catechins and 40 % (75 mg) epigallocatechin gallate (EGCG)]	
Quercetin	125 mg
Vitamin C (as ascorbic acid)	100 mg
Zinc (as zinc bisglycinate)	15 mg

**Inactive Ingredients:** : Capsule (hydroxypropylmethylcellulose),

magnesium stearate (vegetable), and silica.

This product is suitable for Vegetarians gluten free, non-GMO and Sugar Free.

#### PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

#### INDICATION & PHARMACOLOGICAL ACTION

**IMMUNE ACTIVE™** provides vitamin C and zinc and features quercetin and EGCG to help support a healthy immune response and promote antioxidant processes.

Ingredients	Uses for ingredient
L-Cysteine (as N-acetyl-L-cysteine)	The main benefits of NAC come from the supplement's antioxidant and anti-inflammatory properties. Antioxidants are compounds that help fight disease in your body. Anti-inflammatories reduce swelling and irritation in your body's tissues.
Decaffeinated Green Tea (Camellia sinensis)	Decaffeinated green tea (Camellia sinensis) may have immune-boosting properties due to its antioxidant and polyphenol content
Quercetin	Quercetin prevents immune cells from releasing histamines, which are chemicals that cause allergic reactions.
Vitamin C (as ascorbic acid)	Vitamin C stimulates neutrophil migration to the site of infection, enhances phagocytosis and oxidant generation, and microbial killing.
Zinc (as zinc bisglycinate)	Zinc bisglycinate supports immune function, skin health, wound healing, cognitive function, and men's reproductive health. Its superior bioavailability ensures better absorption and utilization by the body, enhancing these benefits.

#### CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take **IMMUNE ACTIVE™** 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.

#### WARNING AND SPECIAL PRECAUTIONS

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: Procedures to widen narrowed arteries (angioplasty), Cancer, Seizure disorder, Vitamin B12 deficiency Taking folic acid supplements might improve certain lab tests in people with low vitamin B12 levels (This may make it seem like vitamin B12 deficiency is improved when it isn't. If left untreated, this could cause permanent nerve damage). If you are taking the following medication, please consult with your healthcare professional before taking: Fosphenytoin (Cerebix), Phenobarbital (Luminal), Phenytoin (Dilantin), Primidone used for seizures, Pyrimethamine used to treat parasite infections, 5-Fluorouracil. If any of the following happens, stop using **IMMUNE ACTIVE™** 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 **IMMUNE ACTIVE™**. 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):

- Diarrhoea, Fatigue, Headache, Nausea

These are all very serious effects. If you have them, you may have had a serious reaction to **IMMUNE ACTIVE™**. 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.

#### 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**)

#### DOSAGE AND DIRECTIONS FOR USE

**Adults:** Take one (1) capsule daily with food or as directed by your healthcare practitioner

**Do no take more than the recommended dose.**

#### 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.

#### 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.

#### 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 **IMMUNE ACTIVE™** if you notice visible signs of deterioration.

#### IDENTIFICATION

Clear vegetable Capsule/Yellow Speckled Fill.

#### PRESENTATION

A white 250 ml HDPE bottle with a white cap, induction seal, tamper shrink seal, wadding and silica gel sachet.

#### 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: 50

Kategorie D: Komplementêre medisyne.

Dissipline: Gesondheidsaanvulling

34.12 Meervoudige Bestanddeel Formulasie

HANDELSNAAM EN DOSEERVORM,

## IMMUNE ACTIVE™, 60 Kapsule

### SAMESTELING

Elke (1) kapsule IMMUNE ACTIVE™ bevat die volgende aktiewe stowwe:

L-sisteien (as N-asetiel-L-sisteien)	300 mg
Kafeienvrye groen tee (Camellia sinensis)	187,50 mg
[Blaaerekstrak gestandaardiseer tot 60% (112,50 mg) katekiene en 40% (75 mg) epigallocatechin gallate (EGCG)]	
Quercetin	125 mg
Vitamiën C (as askorbiensuur)	100 mg
Sink (as sinkbisglycinaat)	15 mg

**Onaktiewe bestanddele:** Kapsule (hydroxypropylmethylcellulose), magnesiumstearaat (groente) en silika.

**Hierdie produk is geskik vir vegetêriërs glutenvry, nie-GGO en suikervry**

### FARMAKOLOGIESE KLASIFIKASIE

Komplementêre medisyne

### AANDUIDING EN FARMAKOLOGIESE WERKING

**IMMUNE ACTIVE™** verskaf vitamien C en sink en kenmerke quercetin en EGCG om 'n gesonde immunerespons te ondersteun en bevorder antioksidantprosesse.

Bestanddele	Gebruik vir bestanddeel
L-sisteien (as N-asetiel-L-sisteien)	Die belangrikste voordele van NAC kom uit die aanvulling se antioksidante en anti-inflammatoriese eienskappe. Antioksidante is verbindings wat help om siektes in jou liggaam te beveg. Anti-inflammatoriese middels verminder swelling en irritasie in jou liggaam se weefsels.
Kafeienvrye groen tee (Camellia sinensis)	Kafeienvrye groen tee (Camellia sinensis) kan immuunversterkende eienskappe hê as gevolg van sy antioksidant- en polifenole inhoud
Quercetin	Quercetin verhoed dat immuunselle histamiene vrystel, wat chemikalieë is wat allergiese reaksies veroorsaak.
Vitamiën C (as askorbiensuur)	Vitamiën C stimuleer neutrofiel migrasie na die plek van infeksie, verhoog fagositose en oksidantgenerering, en mikrobiese dood.
Sink (as sinkbisglycinaat)	Sinkbisglycinaat ondersteun immuunfunksie, velgesondheid, wondgenesing, kognitiewe funksie en mans se voortplantingsgesondheid. Die voortreflike biobeskikbaarheid daarvan verseker beter absorpsie en benutting deur die liggaam, wat hierdie voordele verbeter.

### KONTRA-INDIKASIES:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie IMMUNE ACTIVE™ neem as jy hipersensitief (allergies) is vir enige van die bestanddele nie. As jy allergieë het, maak seker dat jy met jou gesondheidsorgpraktisyn gaan praat voordat jy hierdie aanvulling neem.

### WAARSKUWING EN SPESIALE VOORSORGMATREËLS

Indien jy enige van die volgende gedagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik. Prosedures om vernoude are (angioplastiek), kanker, beslagleggingsversteuring, vitamien B12-tekort te verbreed Die neem van foliensuraanvullings kan sekere laboratoriumtoetse verbeter by mense met lae vitamien B12-vlakke (Dit kan dit laat lyk asof vitamien B12-tekort verbeter word as dit nie is nie. As dit nie behandel word nie, kan dit permanente senuweeskade veroorsaak). As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem: Fosfenytoin (Cerebyx), Fenobarbital (Luminal), Fenitoin (Dilantin), Primidone wat gebruik word vir aanvalle, Pyrimethamine wat gebruik word om parasietversteurings te behandel, 5-Fluorouracil. As enige van die volgende gebrue, hou op om IMMUNE ACTIVE™ te gebruik en vertel jou dokter of gaan na die ongevallende 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 jy dit het, het jy dalk 'n ernstige reaksie op IMMUNE ACTIVE™ gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê.

Neuwe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteer aan jou gesondheidsorgpraktisyn as hulle voortduur):

- Diarree, moegheid, hoofpyn, naarheid..
- Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op IMMUNE ACTIVE™ gehad. Miskien het u dringende mediese hulp of hospitalisasie nodig. Raadpleeg 'n gesondheidsorgpraktisyn as u enige mediese toestand het. 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.

### INTERAKSIES

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**)

### DOSIS EN AANWYSINGS VIR GEBRUIK

**Volwasse** Neem daagliks een (1) kapsule saam met kos of soos voorgeskryf deur jou gesondheidsorgpraktisyn.

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

### NEWE-EFFEKTE

Indien jou algemene gesondheid vererger of as jy enige nadelige effekte ervaar tydens die gebruik van hierdie aanvulling, 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 OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN

Sien nuwe-effekte.

#### Behandeling:

Staa gebruik en raadpleeg jou dokter, apteker of ander gesondheidsorgpraktisyn vir advies.

### BERGING INSTRUKSIE

Hou dig toegemaak op 'n koel, droë plek, onder 25 °C. Beskerm teen direkte sonlig en hitte.

Bêre n die oorspronklike bottel.

Hou die bottel styf toe.

Vervang die beskermende dop na elke gebruik.

Moet nie gebruik word na die vervaldatum wat op die bottel aangedui word nie.

Moenie IMMUNE ACTIVE™ gebruik as u sigbare tekens van agteruitgang opmerk nie.

### IDENTIFIKASIE

Duidelike groentekapsule/geel gespikkelde vulsel.

### AANBIEDING

'n Wit 250 ml HDPE-bottel met 'n wit dop, induksiesel, peuterkrimpseël, spons en silikagelsakkie.

### 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.