

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS [S0]

Not scheduled

### PROPRIETARY NAME AND DOSAGE FORM:

VITAFEN® Immune Combo Caplets 30

Each caplet contains:

Ingredients	Elemental value	NRV% *
Vitamin C (as Ascorbic Acid)	1000 mg	1000
Vitamin D <sub>3</sub> (as Cholecalciferol)	1000 iu	167
Zinc (as Zinc Amino Acid Chelate 10%)	25 mg	227
Selenium (as Selenium Amino Acid Chelate 0.2%)	27.5 µg	55

\* South African Nutrient reference values for individuals 4 years and older.

### Other ingredients:

Hypromellose, Magnesium Stearate, Microcrystalline Cellulose, Sodium Starch Glycolate, Talc, Titanium Dioxide, Flexi-Coat® Green Coating Agent. Contains no artificial sweeteners, lactose or sugar.

### PHARMACOLOGICAL CLASSIFICATION

34.12 Category D (Health Supplement) [S0]

### INDICATIONS

Contributes to:

- Cell protection from free radical damage (Vitamin C is an antioxidant).
- The normal function of the immune system and the maintenance of good health.
- Iron absorption from food.
- The absorption and use of calcium and phosphorous.
- Normal collagen formation for the normal functioning of blood vessels, cartilage, bones, gums, skin and teeth.
- Normal energy-yielding metabolism and functioning of the nervous system.
- Protection of cells from oxidative stress, reduction of tiredness and fatigue.
- Connective tissue formation and metabolism of carbohydrates, fats and proteins.
- Normal acid-base metabolism, cognitive function, DNA synthesis, fertility & reproduction, macronutrient and Vitamin A metabolism.
- The normal process of cell division.
- Normal thyroid function.

“A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance.”

### CONTRAINDICATIONS

Hypersensitivity to any of the ingredients.

If you are pregnant or breastfeeding your baby, please consult your health care provider for advice before taking this medicine. Not permitted for use in children under the age of 18 (Selenium supplementation is not permitted in children under 18).

### WARNINGS AND SPECIAL PRECAUTIONS

Do not exceed the recommended dose.

Follow all directions on your medicine label. Always tell your healthcare provider if you are taking any other medicine. You should not use this product if you have ever had an allergic reaction to the listed ingredients.

Ask a doctor or pharmacist about using this product if you have any of the following:

- Under-active thyroid (hypothyroidism).
- Hyperoxaluria; Kidney disease or a history of kidney stones; Hereditary iron overload disorder (hemochromatosis).
- Diabetes mellitus; Glucose-6-phosphate dehydrogenase deficiency.
- Nonmelanoma skin cancer, long-term use of selenium supplements might slightly increase the risk of cancer recurrence. Until more is known, avoid long-term use of selenium supplements if you have ever had skin cancer.
- Disturbances of calcium metabolism, e.g. hypercalcaemia.

Selenium might increase the risk of bleeding during and after surgery. Stop taking selenium at least 2 weeks before a scheduled surgery.

### KEEP OUT OF REACH OF CHILDREN.

### INTERACTIONS

Drug interactions may occur if vitamin C is taken together with:

- Protease inhibitors; Oestrogens (estrogens); Warfarin; anti-acid (aluminium) products.

Drug interactions may occur if Zinc is taken together with:

#### Antibiotics (Tetracycline- and Quinolone antibiotics):

- Zinc can attach to tetracyclines in the stomach. This decreases the amount of tetracyclines that can be absorbed and zinc with tetracyclines might decrease the effectiveness of tetracyclines. To avoid this interaction, take zinc 2 hours before or 4 hours after taking tetracyclines.
- Zinc might decrease antibiotics absorption and might decrease the effectiveness of some antibiotics. To avoid this interaction, take zinc supplements at least 1 hour after antibiotics.

#### Cisplatin (Platinol-AQ)

- Is used to treat cancer. Taking zinc along with EDTA and cisplatin (Platinol-AQ) might increase the effects and side effects of cisplatin (Platinol-AQ).

#### Penicillamine

- Penicillamine is used for Wilson's disease and rheumatoid arthritis. Zinc might decrease how much penicillamine your body absorbs and decreases the effectiveness of penicillamine.

Drug interactions may occur if Selenium is taken together with:

- Blood thinners like Warfarin (Coumadin); Sedative medications (Barbiturates).

Interactions with these ingredients may increase the risk of developing side effects or reduce the effectiveness of the medicine. Always consult your healthcare provider if you are using any other medications.

### DOSAGE AND DIRECTIONS FOR USE

Adults: Take 1 caplet per day, with a glass of water after a meal.

Do not share medicines prescribed for you with any other person. In the event of over-dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

### SIDE EFFECTS

Ascorbic acid may cause some unwanted effects. If any side effects do occur, i.e. back pain, they may need medical attention. Seek immediate healthcare advice.

Vitamin D<sub>3</sub> might cause:

- Skin rash or irritation, coughing, dizziness, abdominal cramps, nausea, diarrhoea and rapid heartbeat.

Selenium might cause:

- Muscle tenderness, light-headedness, tremor, facial flushing, blood clotting problems, liver and kidney problems.
- High doses might cause nausea, vomiting, nail changes, loss of energy, and irritability.
- Poisoning from long-term use is similar to arsenic poisoning, with symptoms including hair loss, white horizontal streaking on fingernails, nail inflammation, fatigue, irritability, nausea, vomiting, garlic breath odour, and a metallic taste.

Zinc is **LIKELY SAFE** for most adults when taken by mouth in amounts not larger than 40 mg per day.

Zinc might cause:

- High doses might cause fever, coughing, stomach pain, fatigue, and many other problems.
- Diarrhoea, stomach cramps, headache, and nausea.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any side effects while taking this medicine, please consult your health care provider for advice.

#### **STORAGE INSTRUCTIONS**

Close the container properly after usage. Store in a cool, dry place below 25 °C. Do not leave the container open or store it in a fridge.

**STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**

#### **PRESENTATION**

Silver with Silver lid packaged container with tamperproof induction seal and a silica gel sachet. Clearly labelled with detailed information printed on the label. Containing 30 green coated oval-shaped caplets.

#### **IDENTIFICATION**

Green coated oval-shaped caplets.

#### **REGISTRATION NUMBER**

To be allocated.

#### **APPLICANT**

Pharmafen (Pty) Ltd  
449, 34th Avenue, Villieria,  
Pretoria, 0186, South Africa.  
Email: [info@pharmafen.co.za](mailto:info@pharmafen.co.za)  
Website: [www.pharmafen.co.za](http://www.pharmafen.co.za)

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#### **DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET**

April 2022

#### **Complementary Medicine: Health Supplement**

#### **Classification D (HS)**

This medicine has not been evaluated by the SAHPRA for its quality, safety or intended use. This medicine is not intended to diagnose, treat, cure or prevent any disease.

**SKEDULERINGSTATUS [S0]**

Nie geskeduleer nie

**HANDELSNAAM EN DOSERINGSVORM:**

VITAFEN® Immun Kombinasie Kaplette 30

Elke kaplet bevat:

Bestanddele	Elementêre waarde	NRV% *
Vitamiën C (as Askorbiensuur)	1000 mg	1000
Vitamiën D <sub>3</sub> (as Cholekalsiferol)	1000 iu	167
Sink (as Sink Aminosuurchelaat 10%)	25 mg	227
Seleen (as Seleen Aminosuurchelaat 0.2%)	27.5 µg	55

\* Suid Afrikaanse Voedings verwysingswaardes vir persone 4 jaar en ouer.

**Ander bestanddele:**

Hipomellose, Magnesiumstearaat, Mikrokrystalien Sellulose, Natrium Stysel Glykoolaat, Talk, Titaniumdioksied, Flexi-Coat® Groen Deklaag Agent. Bevat geen suiker, laktose of kunsmatige versoeter.

**FARMAKOLOGIESE KLASSIFIKASIE**

34.12 Kategorie D (Gesondheidsaanvuller) [S0]

**INDIKASIES**

Dra by tot:

- Selbeskerming teen vrye radikale skade (Vitamiën C is 'n antioksidant).
- Die normale funksie van die immuunstelsel en die handhawing van goeie gesondheid.
- Ysterabsorpsie uit voedsel.
- Die absorpsie en gebruik van kalsium en fosfor.
- Normale kollageenvorming vir die normale funksionering van bloedvate, kraakbeen, bene, tandvleis, vel en tande.
- Normale energie-lewerende metabolisme en funksionering van die senuweestelsel.
- Beskerming van selle teen oksidatiewe stres en die vermindering van moegheid.
- Bindweefselvorming en metabolisme van koolhidrate, vette en proteïene.
- Normale suur-basis metabolisme, kognitiewe funksie, DNA-sintese, vrugbaarheid & voortplanting, makrovoedingstof en Vitamiën A metabolisme.
- Die normale proses van seldeling.
- Normale skildklierfunksie.

“n Omvattende en gebalanseerde eetplan is die mees doeltreffend- en veiligste manier vir die handhawing van goeie gesondheid om geestelike en fisiese doelwitte te bereik.”

**KONTRA-INDIKASIES**

Hipersensitiwiteit vir enige van die bestanddele.

Indien swanger of borsvoed, raadpleeg jou gesondheidsorgverskaffer voordat hierdie medisyne gebruik word.

Nie toegelaat vir gebruik by kinders onder die ouderdom van 18 nie (Seleenaanvulling word nie toegelaat by kinders onder 18 nie).

**WAARSKUWINGS EN SPESIALE VOORSORGMATREËLS**

Moenie die aanbevole dosis oorskry nie.

Volg altyd die aanwysings op die etiket. Raadpleeg altyd u gesondheidsorgverskaffer indien u enige ander medikasie gebruik. Indien u al voorheen enige allergiese reaksie getoon het op die gelyste bestanddele, raadpleeg u gesondheidsorgverskaffer.

Vra 'n dokter of apteker oor die gebruik van hierdie produk as jy enige van die volgende het:

- Onderaktiewe skildklier (hipotireose).
- Hiperoksalurie; Niersiekte of 'n geskiedenis van nierstene; Oorerflike ysteroorladingsversteuring (hemochromatose).
- Diabetes mellitus; Glukose-6-fosfaat dehidrogenase tekort.
- Nie-melanoom velkanker, langtermyn gebruik van seleenaanvullings kan die risiko van herhaling van kanker effens verhoog. Totdat meer bekend is, vermy langtermyngebruik van seleenaanvullings as jy al ooit velkanker gehad het.
- Versteurings van kalsiummetabolisme, bv. hiperkalsemie.

Seleen kan die risiko van bloeding tydens en na operasies verhoog. Hou op om seleen te neem ten minste 2 weke voor 'n geskeduleerde operasie.

**HOU BUITE BEREIK VAN KINDERS.****INTERAKSIES**

Geneesmiddelinteraksies kan voorkom as vitamien C saam met:

- Protease-inhibeerders; Oestrogeen (estrogene); Warfarin; anti-suur (aluminium) produkte.

Geneesmiddelinteraksies kan voorkom as sink saam met:

**Antibiotika (tetrasiklien- en kinolone-antibiotika):**

- Sink kan aan tetrasikliene in die maag heg. Dit verminder die hoeveelheid tetrasikliene wat geabsorbeer kan word en sink met tetrasikliene kan die doeltreffendheid van tetrasikliene verminder. Om die interaksie te vermy, neem sink 2 uur voor of 4 uur na die inname van tetrasikliene.
- Sink kan die absorpsie van antibiotika verminder en kan die doeltreffendheid van sommige antibiotika verminder. Om hierdie interaksie te vermy, neem sinkaanvullings ten minste 1 uur na antibiotika.

**Cisplatin (Platinol-AQ)**

- Word gebruik om kanker te behandel. Inname van sink saam met EDTA en cisplatin (Platinol-AQ) kan dalk die effekte en nuwe-effekte van cisplatin (Platinol-AQ) vermeerder.

**Penisillamiene**

- Penisillamiene word gebruik vir Wilson se siekte en rumatoïede artritis. Sink kan die hoeveelheid verminder wat jou liggaam absorbeer en verminder die doeltreffendheid van penisillamiene.

Geneesmiddelinteraksies kan voorkom as Seleen saam met:

- Bloedverdunders soos Warfarin (Coumadin); Kalmeermiddels (Barbiturate).

Interaksies met hierdie bestanddele kan die risiko om nuwe-effekte te ontwikkel verhoog of die effektiwiteit van die medisyne verminder. Raadpleeg altyd u gesondheidsorgverskaffer as u enige ander medikasie gebruik.

**DOSERING EN GEBRUIKSAANWYSINGS:**

Volwassenes: Neem 1 kaplet per dag, met 'n glas water na 'n maaltyd.

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie. In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

**NEWE-EFFEKTE**

Askorbiensuur kan sekere nuwe-effekte veroorsaak. As enige nuwe-effekte voorkom, byvoorbeeld rugpyn, kan mediese hulp nodig wees. Kry onmiddellike gesondheidsadvies.

Vitamiën D<sub>3</sub> kan dalk die volgende veroorsaak:

- Veluitslag of irritasie, hoes, duiseligheid, buikkrampe, naarheid, diarree en vinnige hartklop.

Seleen kan dalk die volgende veroorsaak:

- Spierteerheid, lighoofdigheid, bewing, gesigspoeling, bloedstollingsprobleme, lewer- en nierprobleme.
- Hoë dosisse kan naarheid, braking, naelveranderinge, verlies aan energie en prikkelbaarheid veroorsaak.
- Vergiftiging as gevolg van langdurige gebruik is soortgelyk aan arseenvergiftiging, met simptome wat haarverlies, wit horisontale strepe op vingernaels, naelontsteking, moegheid, prikkelbaarheid, naarheid, braking, knoffelasemreuk en 'n metaalsmaak insluit.

Sink is **WAARSKYNLIK VEILIG** vir die meeste volwassenes wanneer dit per mond ingeneem word in hoeveelhede nie groter as 40 mg per dag nie.

Sink kan kan dalk die volgende veroorsaak:

- Hoë dosisse kan koors, hoes, maagpyn, moegheid en vele ander probleme veroorsaak.
- Diarree, maagkrampe, hoofpyn en naarheid.

Nie alle nuwe-effekte is in hierdie pamflet gelys nie. Indien u algemene gesondheidstoestand versleg of as u enige nuwe-effekte ervaar terwyl u hierdie medisyne gebruik, raadpleeg u gesondheidsorgverskaffer vir advies.

#### **BERGINGSINSTRUKSIES**

Verseël die houer behoorlik na gebruik. Bêre op 'n koel, droë plek onder 25 °C. Moenie die houer oop laat of in die yskas bêre nie.

#### **STOOR ALLE MEDISYNE BUITE BEREIK VAN KINDERS.**

#### **AANBIEDING**

Verpak in 'n Silwer houer, met 'n Silwer deksel en 'n peuterbestande induksie-seël en 'n silikagel sakkie. 'n Gedrukte etiket met volledige aanwysings is op die houer aangebring. Bevat 30 groen bedekte ovaalvormige kaplette.

#### **IDENTIFIKASIE**

Groen bedekte ovaalvormige kaplette.

#### **REGISTRASIE NOMMER**

Om toegeken te word.

#### **AANSOEKER**

Pharmafen (Pty) Ltd

449, 34th Avenue, Villieria,

Pretoria, 0186, South Africa.

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Website: [www.pharmafen.co.za](http://www.pharmafen.co.za)

® = Geregistreerde handelsmerk

#### **DATUM VAN PUBLIKASIE VAN HIERDIE PASIËNT INLIGTING PAMFLET**

April 2022

#### **Aanvullende Medisyne: Gesondheidsaanvuller**

#### **Klassifikasie: D (HS)**

Hierdie medisyne is nie deur SAHPRA geëvalueer ten opsigte van die kwaliteit, veiligheid of beoogde gebruik daarvan nie. Hierdie medisyne is nie bedoel vir die diagnose, behandeling, genesing of voorkoming van enige siekte nie.