

SCHEDULING STATUS [S0]

Not scheduled

PROPRIETARY NAME AND DOSAGE FORM:

VITAFEN® Vitamin C Slow Release Caplets 30

Each caplet contains:

Ingredients	Elemental value	NRV% *
Vitamin C (as Ascorbic Acid)	1000 mg	1000
Citrus Aurantium L 4:1 Extract (providing Hesperidin)	7.5 mg 2.625mg	** **

* 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® Yellow Coating Agent. Contains no artificial sweeteners, lactose or sugar.

PHARMACOLOGICAL CLASSIFICATION

34.12 Category D (Health Supplement) [S0]

INDICATIONS

VITAFEN® Vitamin C Slow Release caplets provide the gradual release of vitamin C over time.

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.
- 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 fats and proteins.

“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 (Citrus Bioflavonoid 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 ascorbic acid if you have ever had an allergic reaction to a vitamin C supplement.

Ask a doctor or pharmacist about using ascorbic acid if you have any of the following:

- Hyperoxaluria; Kidney disease or a history of kidney stones; Hereditary iron overload disorder (hemochromatosis).
- Diabetes mellitus; Glucose-6-phosphate dehydrogenase deficiency.

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.

These vitamin C interactions can increase your risk of developing side effects or reduce the effectiveness of the medications. Always consult your healthcare professional if you are taking any other medicine.

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.

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 yellow coated oval-shaped caplets.

IDENTIFICATION

Yellow coated oval-shaped caplets.

REGISTRATION NUMBER

To be allocated.

APPLICANT

Pharmafen (Pty) Ltd
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Pretoria, 0186, South Africa.
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Website: www.pharmafen.co.za

® = Registered trademark

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® Vitamien C Stadige Vrystelling Kaplette 30

Elke kaplet bevat:

Bestanddele	Elementêre waarde	NRV% *
Vitamien C (as Askorbiensuur)	1000 mg	1000
Sitrus Aurantium L 4:1 Ekstrak (voorsien Hesperidien)	7.5 mg 2.625mg	** **

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

Ander bestanddele:

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

FARMAKOLOGIESE KLASSIFIKASIE

34.12 Kategorie D (Gesondheidsaanvuller) [S0]

INDIKASIES

VITAFEN® Vitamien C Stadige Vrystelling kaplette verskaf die geleidelike vrystelling van vitamien C oor tyd.

Dra by tot:

- Selbeskerming teen vrye radikale skade (Vitamien C is 'n antioksidant).
- Die normale funksie van die immuunstelsel en die handhawing van goeie gesondheid.
- Ysterabsorpsie uit voedsel.
- 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.
- Vorming van bindweefsel en metabolisering van vette en proteïene.

“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 (Sitrus Bioflavonoïed aanvulling 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 met die gebruik van askorbiensuur, raadpleeg u gesondheidsorgverskaffer.

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

- Hiperoksalurie; Niersiekte of 'n geskiedenis van nierstene; Oorerflike ysteroorladingsversteuring (hemochromatose).
- Diabetes mellitus; Glukose-6-fosfaat dehidrogenase tekort.

INTERAKSIES

Geneesmiddelinteraksies kan voorkom as vitamien C saam met:

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

Interaksies met Vitamien C 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.

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

BERGINGSINSTRUKSIES

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

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

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

IDENTIFIKASIE

Geel bedekte ovaalvormige kaplette.

REGISTRASIE NOMMER

Om toegeken te word.

AANSOEKER

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* = 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 diagnosering, behandeling, genesing of voorkoming van enige siekte nie.