

Patient Information Leaflet

SCHEDULING STATUS [S0]

Not scheduled

PROPRIETARY NAME AND DOSAGE FORM:

Vitatech Selenium Tablets 30

Each tablet contains:

Ingredient:	Elemental value	NRV %
Selenium (as Amino Acid Chelate)	55,0 mcg	100

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

PHARMACOLOGICAL CLASSIFICATION

34.7 Category D (Health Supplement) [S0]

Other ingredients:

Microcrystalline cellulose, di-calcium phosphate & magnesium stearate

Contains no sugar or artificial sweetener.

INDICATIONS

Contributes to

- the protection of cells from oxidative stress
- normal spermatogenesis
- the maintenance of normal hair
- the maintenance of normal nails
- the normal function of the immune system
- normal thyroid function

An antioxidant for the maintenance of good health

A factor in the maintenance of good health.

“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 breast feeding your baby, please consult your health care provider for advice before taking this medicine.

WARNINGS AND SPECIAL PRECAUTIONS

Do not exceed the recommended dosage.

High doses might cause toxicity, and in HIV-positive women, it might increase virus levels in breast milk.

Autoimmune diseases: Selenium might stimulate the immune system. In theory, selenium might make autoimmune disease worse by stimulating the activity of the disease. People with autoimmune diseases such as multiple sclerosis, systemic lupus erythematosus (SLE), rheumatoid arthritis (RA), and other should avoid taking selenium supplements.

Hemodialysis: Blood levels of selenium can be low in people undergoing hemodialysis. Using a dialysis solution with selenium might increase selenium levels, but selenium supplementation might be needed for some people.



Under-active thyroid (hypothyroidism): Taking selenium can worsen hypothyroidism especially in people with iodine deficiency. In this case, you should take iodine along with selenium. Check with your healthcare provider.

Fertility problems in men: Selenium might decrease the ability of sperm to move, which could reduce fertility. If you are trying to father a child, don't take selenium supplements.

Skin cancer: In people who have had 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.

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

Follow all directions on your medicine label and package. Always inform your healthcare provider if you are taking any other medicine

INTERACTIONS

Medicines that will interact with Selenium are:

- slow blood clotting (Anticoagulant / Antiplatelet drugs),
- for lowering cholesterol (Statins),
- vitamin E, vitamin C, and beta-carotene might decrease some of the beneficial effects of niacin. Niacin can increase the good cholesterol. It might decrease how well niacin works for increasing good cholesterol,
- sedative medications (Barbiturates) and
- blood thinners like Warfarin (Coumadin)

Minor interactions:

- Birth control pills (Contraceptive drugs) and
- Gold salts include aurothioglucose (Solganal), gold sodium thiomalate (Aurolate), and auranofin (Ridaura).

Always consult your healthcare professional if you are taking any other medicine.

DOSAGE AND DIRECTIONS FOR USE

Adults: Take 1 tablet 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

Selenium can cause:

- muscle tenderness, tremor, light-headedness, facial flushing, blood clotting problems, liver and kidney problems,
- High doses can 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.

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 when taking this medicine, please consult your health care provider for advice. Routine zinc supplementation is not recommended without the advice of a healthcare professional.

STORAGE INSTRUCTIONS

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

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

**PRESENTATION**

White with Green lid packaged container with tamperproof induction seal, labelled with clear, detailed information printed on the label. Containing 30 tablets.

IDENTIFICATION

White, round or oval tablet

REGISTRATION NUMBER

To be allocated.

NAME AND BUSINESS ADDRESS OF THE APPLICANT

Serfie Imports & Exports (PTY) Ltd
Cnr Parkin & Delson Street, North End, Gqeberha 6001
Tel no: +27 (0) 41 816 3100
Email: info@vitatechhealth.com
Website: www.vitatechhealth.com

DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET

October 2021

**Complementary Medicine: Health Supplement
Classification D (HS)**

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

Pasiënt Inligtingsblaadjie

SKEDULERINGSSTATUS [S0]

Nie geskeduleer nie

HANDELSNAAM EN DOSERINGSVORM:

Vitatech Selenium tablette 30

Elke tablet bevat:

Bestanddeel:	Elementeel	NRV %
Selenium (as Aminosuurchelaat)	55,0 mcg	100

* Suid Afrikaanse Voedings verwysingswaardes vir persone 4 jaar en ouer

FARMAKOLOGIESE KLASSIFIKASIE

34.7 Kategorie D (Gesondheidsaanvuller) [S0]

Ander bestanddele

Mikrokristaliese sellulose, di-kalsiumfosfaat & magnesiumstearaat

Bevat geen suiker of kunsmatige versoeter.

INDIKASIES

Dra by tot

- die beskerming van selle teen oksidatiewe stres
- normale spermatogenese
- die handhawing van normale hare
- die handhawing van normale naels
- die normale funksie van die immuunstelsel
- normale skildklierfunksie.

'n Antioksidant om goeie gesondheid te handhaaf

'n Faktor vir die handhawing van goeie gesondheid.

“'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.”

KONTRAINDIKASIES

Hipersensitiwiteit vir enige van die bestanddele.

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

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS

Moenie die aanbevole dosis oorskry nie.

Hoë dosisse kan toksisiteit veroorsaak, en by MIV-positiewe vroue kan dit die virusvlakke in borsmelk verhoog.

Auto -immuun siektes: Selenium kan die immuunstelsel stimuleer en kan dit outo -immuun siektes vererger deur die aktiwiteit van die siekte te stimuleer. Mense met outo -immuun siektes, soos veelvuldige sklerose, sistemiese lupus erythematosus (SLE), rumatoïede artritis (RA) en ander, moet nie seleniumaanvullings gebruik nie.

Hemodialise: Bloedvlakke met selenium kan laag wees by mense wat hemodialise ondergaan. Die gebruik van 'n dialise -oplossing met selenium kan seleniumvlakke verhoog, terwyl seleniumaanvulling vir sommige mense nodig mag wees.



Onderaktiewe skildklier (hipotireose): Die gebruik van selenium kan hipotireose vererger, veral by mense met 'n jodiumtekort. In sulke gevalle moet u jodium saam met selenium geneem word.

Vrugbaarheidsprobleme by mans: Selenium kan die beweeglikheid van sperm verminder, wat vrugbaarheid kan verminder. Moenie seleniumaanvullings neem as u 'n kind wil verwek nie.

Velkanker: By mense wat nie-melanoom velkanker gehad het, kan langdurige gebruik van seleniumaanvullings die risiko van herhaling van kanker effens verhoog. Vermyn langdurige gebruik van seleniumaanvullings as u ooit velkanker gehad het.

Operasies: Selenium kan die risiko van bloeding tydens en na die operasie verhoog. Hou op om selenium te neem ten minste 2 weke voor 'n geskeduleerde operasie.

Word nie vir kinders aanbeveel < 3 jaar. **HOU BUIITE BEREIK VAN KINDERS**

INTERAKSIES

Die volgende medisyne kan interaksies veroorsaak:

- stadige bloedstolling (antistollings- / anti -plaatjie -middels),
- vir die verlaging van cholesterol (statiene),
- vitamien E, vitamien C en beta-karoteen kan sommige van die voordelige gevolge van niasien verminder. Niasien kan die goeie cholesterol verhoog. Die afname van die effektiewe werking van niasien werk is moontlik wat help om goeie cholesterol te verhoog,
- kalmeermiddels (Barbiturate) en
- bloedverdunners soos Warfarin (Coumadin)

Geringe interaksies:

- Voorbehoedpille (voorbehoedmiddels) en
- Goue soute sluit in aurothioglucose (Solganal), goudnatriumtiomalaat (Aurolate) en auranofien (Ridaura).
-

Raadpleeg altyd u gesondheidsorgverskaffer as u enige ander medikasie gebruik.

DOSERING EN GEBRUIKSAANWYSINGS:

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

Moenie medisyne met 'n ander persoon deel nie. In die geval van 'n oordosis, raadpleeg dadelik u gesondheidsorgverskaffer. Indien nie beskikbaar, kontak die naaste hospitaal of mediese sentrum vir advies.

NEWE-EFFEKTE

Moontlike newe-effekte:

- spierslapheid, bewing, lighoofdigheid, gesigspoeling, bloedstollingsprobleme, lewer- en nierprobleme,
- Hoë dosisse kan naarheid, braking, naelveranderings, energieverlies en prikkelbaarheid veroorsaak.
- Vergiftiging as gevolg van langdurige gebruik is soortgelyk aan arseenvergiftiging, met simptome soos haarverlies, wit horisontale strepe op naels, spykerontsteking, moegheid, prikkelbaarheid, naarheid, braking, knoffelasem en 'n metaal smaak mag veroorsaak.

Nie alle newe-effekte is in hierdie pamflet gelys nie. Indien u algemene gesondheidstoestand versleg of as u enige newe-effekte ervaar, raadpleeg u gesondheidsorgverskaffer vir advies. Roetine sinkaanvullings word nie aanbeveel sonder die advies van 'n gesondheidsverskaffer nie.

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 BUIITE BEREIK VAN KINDERS.

**AANBIEDING**

Verpak in 'n Wit houer met Groen deksel en 'n peuterbestande induksie-seël. 'n Gedrukte etiket met volledige aanwysings is op die houer aangebring. Bevat 30 tablette.

IDENTIFIKASIE

Wit ronde of ovaal tablet

REGISTRASIE NOMMER

Nie toegeken nie.

NAAM EN BESIGHEIDSADRES VAN DIE AANSOEKER

Serfie Invoere & Uitvoere (Edms.) Bpk

H/v Parkin & Delsonstrate, North End, Gqeberha 6001

Tel no: +27 (0) 41 816 3100

e-Posadres: info@vitatechhealth.com

Webwerf: www.vitatechhealth.com

DATUM VAN PUBLIKASIE VAN HIERDIE PASIËNT INLIGTING PAMFLET

Oktober 2021

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.