

PROFESSIONAL INFORMATION

SCHEDULING STATUS

S0

1. NAME OF THE MEDICINE

Vitatech Selenium Tablets 30

2. COMPOSITION

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

For full list of excipients, see section 6.a

3. PHARMACEUTICAL FORM

White, round or oval tablet.

4. CLINICAL PARTICULARS

(a) Therapeutic indication

The selenium in **Vitatech Selenium** assist to maintain optimal nutritional support and wellness in the form of good health through a biochemical process at cellular level. It plays a key role in metabolism and has antioxidant properties that protect the cells in your body. Selenium is important for making many body processes work correctly. It seems to increase the action of antioxidants.

(b) Dosage and method of administration

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

Do not exceed the recommended dose.

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

Only take the medication as indicated on the packet or container.

If you skip a dose, do not take a double dose.

Take at least two hours before of after taking other medication.

(c) Contraindications

Hypersensitivity to any of the ingredients or the excipients. Not for use in children under the age of 18 years.

(d) Special warnings and precautions for use

Vitatech Selenium should be used with care if patients have any of these health problems:

- Autoimmune diseases: 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,

- haemodialysis: Blood levels of selenium can be low in people undergoing haemodialysis. 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.
- 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.

Taking doses above 400 mcg can increase the risk of developing selenium toxicity. Taking lower doses for a long time, such as doses that are higher than the recommended nutrient reference values (NRV's), can also increase the risk of developing diabetes.

Any other supplementation consisting of vitamins and minerals should be taken into account when prescribing / suggesting **VITATECH SELENIUM**.

(e) Interaction with other medicines and other forms of interaction

No interaction studies have been performed on **VITATECH SELENIUM**, however the below information gathered from the literature on the active ingredients should be taken into consideration:

Vitatech Selenium may interact with the following medicines. Caution is advised when used concurrently:

- anticoagulant / Antiplatelet medications that slow blood clotting. Selenium might slow blood clotting. Taking selenium along with medications that also slow clotting might increase the chances of bruising and bleeding, e.g., warfarin (Coumadin), and others.
- statins used for lowering cholesterol - selenium, beta-carotene, vitamin C, and vitamin E together might decrease the effectiveness of some medications used for lowering cholesterol.
- niacin along with selenium, vitamin E, vitamin C, and beta-carotene might decrease some of the beneficial effects of niacin. Niacin can increase the good cholesterol. Taking selenium along with these other vitamins might decrease the how well niacin works for increasing good cholesterol.
- barbiturates - sedative medications the body breaks down medications to get rid of them. Selenium might slow how fast the body breaks down sedative medications. It might increase the effects and side effects of these medications. Warfarin. Selenium might also increase the effects of warfarin in the body. Taking selenium along with warfarin might increase the chances of bruising and bleeding.

Minor Interaction:

- Birth control pills (Contraceptive drugs). Some research shows that women who take birth control pills might have increased blood levels of selenium. But other research shows no change in selenium levels in women who take birth control pills. Some birth control pills include ethinyl estradiol and levonorgestrel

(Triphasil), ethinyl estradiol and norethindrone (Ortho-Novum 1/35, Ortho-Novum 7/7/7), and others.

- Gold salts - gold salts bind to selenium and decrease selenium in parts of the body. This might decrease the normal activity of selenium, possibly resulting in symptoms of selenium deficiency.

If you are pregnant or breastfeeding, before using **VITATECH SELENIUM**, please consult your health care provider

(f) Ability to drive and use machines

VITATECH SELENIUM should not affect the ability of individuals to drive or operate machinery.

(g) Side Effects

Can cause side effects such as:

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

High doses of selenium can cause significant side effects including:

- 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.

(h) Overdose

In the event of over-dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

(i) Effects when no further used

There should be no side effects or any withdrawal symptoms after you stop using **VITATECH SELENIUM**

(5) PHARMACOLOGICAL PROPERTIES

(a) PHARMACOLOGICAL CLASSIFICATION

34.7 Category D (Health Supplement) [S0]

(b) PHARMACOLOGICAL ACTION

- Selenium is part of glutathione peroxidase, which protects cell components from oxidative damage due to peroxides produced in cellular metabolism.
- Selenium is used to treat or prevent selenium deficiency.
- Selenium has been used in alternative medicine as an aid to treat Hashimoto's thyroiditis (an autoimmune disorder of the thyroid), and to treat high cholesterol.
- Essential nutrients are substances required by the body to perform its basic functions and must be obtained from our diet since the human body cannot produce them. They have one or more of three basic functions: to provide energy, contribute to body structure, and/or regulate chemical processes in the body.
- They're essential for many body functions, including building strong bones and teeth, regulating your metabolism, and staying properly hydrated. These basic functions allow us to detect and respond to environmental surroundings, move, excrete wastes, breathe, grow, and reproduction.
- When essential nutrients are in short supply or is not able to be utilized properly, a specific deficiency syndrome may be the result.
- When the deficient nutrient is resupplied before irreversible damage occurs, the signs and symptoms are reversed. Deficiency of essential nutrients is noticeable in several symptoms that can be easily observed and includes, but are not limited to, for example: weakness, tiredness, decrease in energy which can also lead to the risk of developing illnesses and health problems.

(6) PHARMACEUTICAL PARTICULARS

(a) Other ingredients

Microcrystalline cellulose, di-calcium phosphate & magnesium stearate

(b) Shelf life

2 years

(c) Storage conditions

Store at or below 25 °C.

Protect from sunlight and moisture.

Keep out of reach of children

Store in original packaging

Do not store in a fridge

Always seal the container properly before storage

(d) Presentation and packaging

White with green lid packaged container with tamperproof induction seal

Clearly labelled with detailed information printed on the label.

Containing 30 tablets.

(e) Disposal and handling

Wrap the contents and the container properly in put in a plastic bag.

Dispose the wrapped package in the normal household waste bag

(7) NAME AND ADDRESS OF REGISTRATION HOLDER

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

(8) REGISTRATION NUMBER

To be allocated

(9) DATE OF PUBLICATION OF PROFESSIONAL INFORMATION

August 2021

(10) COMPLEMENTARY MEDICINE

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.