



Selenium

200mg

PACKAGE INSERT OF HERBIEVITE – SELENIUM (TABLETS)

Western Herbal Complementary Medicine and Health Supplement.

HERBIEVITE – SELENIUM is unregistered and 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.

SCHEDULING STATUS

Not scheduled

NAME OF THE MEDICINE

HERBIEVITE – SELENIUM (tablets)

QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Each tablet contains: 200 µg Selenium

PHARMACEUTICAL FORM

Tablets, HERBIEVITE – SELENIUM: White, round tablet.

CLINICAL PARTICULARS

THERAPEUTIC INDICATIONS

HERBIEVITE – SELENIUM is used for selenium deficiency. Symptoms may include an underactive thyroid and high blood pressure during pregnancy.

HERBIEVITE – SELENIUM helps to fight free radical damage, contributes to clear healthy skin, hair and nails and contributes to the protection of cells from oxidative stress.

HERBIEVITE – SELENIUM helps with the normal function of the immune system, helps the body to recycle Vitamin E for added antioxidant support in the maintenance of good health and may support heart health.

POSOLOGY AND METHOD OF ADMINISTRATION

Take 1 tablet daily before or after a meal, or as directed by your healthcare practitioner.

CONTRAINDICATIONS

HERBIEVITE – SELENIUM must not be used in patients with hypersensitivity to the active substance (Selenium)

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

- HERBIEVITE – SELENIUM should be taken with caution during pregnancy and breastfeeding in doses more than 400 mcg as this may cause toxicity, and in HIV-positive women, might increase virus levels in breast milk (refer to section 4.6 Fertility, pregnancy and lactation)
- HERBIEVITE – SELENIUM should not be taken by patients with autoimmune diseases such as multiple sclerosis, systemic lupus erythematosus (SLE), rheumatoid arthritis (RA), and other.
- 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.
- Taking HERBIEVITE – SELENIUM can worsen hypothyroidism especially in people with iodine deficiency. In this case, you should take iodine along with HERBIEVITE – SELENIUM. Check with your healthcare provider.
- Long-term use of HERBIEVITE – SELENIUM might slightly increase the risk of skin cancer recurrence, but this is controversial. Until more is known about the possible increase in skin cancer risk, avoid long-term use of HERBIEVITE – SELENIUM if you have ever had skin cancer.
- HERBIEVITE – SELENIUM might increase the risk of bleeding during and after surgery. Stop taking HERBIEVITE – SELENIUM at least 2 weeks before a scheduled surgery.

PAEDIATRIC POPULATION: HERBIEVITE – SELENIUM SHOULD NOT BE GIVEN TO INFANTS AND PERSONS UNDER THE AGE OF 18 YEARS.

INTERACTION WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTION

- HERBIEVITE – SELENIUM might slow blood clotting. Taking HERBIEVITE – SELENIUM along with medications that also slow clotting might increase the chances of bruising and bleeding. Some medications that slow blood clotting include aspirin, clopidogrel (Plavix), dalteparin (Fragmin), enoxaparin (Lovenox), heparin, ticlopidine (Ticlid), warfarin (Coumadin), and others.
- Taking HERBIEVITE – SELENIUM, beta-carotene, vitamin C, and vitamin E together might decrease the effectiveness of some medications used for lowering cholesterol. It is not known if selenium alone decreases the effectiveness of some medications used for lowering cholesterol. Some medications used for lowering cholesterol include atorvastatin (Lipitor), fluvastatin (Lescol), lovastatin (Mevacor), and pravastatin (Pravachol).
- Taking HERBIEVITE – SELENIUM along with vitamin E, vitamin C, and beta-carotene might decrease some of the beneficial effects of niacin. Niacin can increase the good cholesterol. Taking HERBIEVITE – SELENIUM along with these other vitamins might decrease the how well niacin works for increasing good cholesterol.
- HERBIEVITE – SELENIUM might slow how fast the body breaks down sedative medications (Barbiturates). Taking HERBIEVITE – SELENIUM with these medications might increase the effects and side effects of these medications.
- Selenium might thin the blood. Selenium might also increase the effects of warfarin (Coumadin) in the body. Taking HERBIEVITE – SELENIUM along with warfarin might increase the chances of bruising and bleeding.
- 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. Gold salts include aurothioglucose (Solganal), gold sodium thiomalate (Aurolate), and auranofin (Ridaura).

FERTILITY, PREGNANCY AND LACTATION

FERTILITY: HERBIEVITE – 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.

PREGNANCY: HERBIEVITE – SELENIUM is possibly unsafe when taken by mouth in doses above 400 mcg daily. This dose might cause toxicity.

BREASTFEEDING: HERBIEVITE – SELENIUM is possibly unsafe when taken by mouth in doses above 400 mcg daily. This dose might cause toxicity, and in HIV-positive women, it might increase virus levels in breast milk

Caution should be exercised when taking HERBIEVITE – SELENIUM while pregnant or breast-feeding. Please consult your healthcare practitioner first if your pregnant or lactating.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

HERBIEVITE – SELENIUM has no effect on your ability to drive vehicles or operate machinery.

UNDESIRABLE EFFECTS

HERBIEVITE – SELENIUM is likely safe for most people when taken by mouth in doses less than or equal to 200 mcg daily for the short-term.

Taking doses above 200 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 dietary allowance (RDA), can also increase the risk of developing diabetes.

HERBIEVITE – SELENIUM can cause side effects such as:

- Muscle tenderness
- Tremor





Selenium

200mg

- Light-headedness
- Facial flushing
- Blood clotting problems
- Liver and kidney problems
- and other side effects

REPORTING OF SUSPECTED ADVERSE REACTIONS.

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to:

- SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>
- CONTEGO PHARMACEUTICALS (Pty) Ltd 250 Nadine Street, Robertville, Roodepoort Gauteng, South Africa

OVERDOSE

High doses of selenium can cause significant side effects including:

- Nausea
- Vomiting
- Nail changes
- Loss of energy
- 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
- Garlic breath odour
- A metallic taste

In case of acute overdose by ingestion of large amount of selenium, gastric lavage and forced diuresis are possible.

PHARMACOLOGICAL PROPERTIES

PHARMACODYNAMIC PROPERTIES

Pharmacological classification: D 32.16 Other – Western Herbal Complementary Medicine.

Selenium is an essential trace element. In human, selenium compounds are glutathione peroxidase and a selenium protein P found in the plasma. In both these proteins, selenium is protein-bound and is present in the form of the amino acid selenocysteine. Other selenium-dependent enzymes are the thioredoxine-reductase and the 5'-deiodinase that catalyses the conversion from tetraiodothyronine (T4) to the active thyroid hormone triiodothyronine (T3)

The selenium-containing glutathionperoxidase is a part of the anti-oxidative protection system of the mammal cell. In case of sufficient quantities of reduced glutathione, the glutathionperoxidase converts a variety of hydroperoxides into relevant alcohols.

The patho-physiological relevance of selenium-dependent reactions has been demonstrated by observations in selenium deficiency. The selenium-containing glutathionperoxidase affects the leucotriene, thromboxane and prostacyclin metabolism. Selenium deficiency inhibits reactions of the immune system, especially the non-specific, cell-bound and humoral reactions. Selenium deficiency affects the activity of a few liver enzymes. Selenium deficiency potentiates oxidatively or chemically induced liver damage and toxicity of heavy metals such as quicksilver and cadmium.

Deficiency of selenium has been associated with an endemic form of cardiomyopathy, Keshan disease. It has also been associated with Kaschin-Beck disease, an endemic osteoarthropathy which causes a severe deformity of the joints.

Clinically manifested selenium deficiency has also been seen to be a result of long-term parenteral nutrition and unbalanced diets. Cardiomyopathies and myopathies are observed most frequently.

PHARMACOKINETIC PROPERTIES

In the blood, selenite is mainly absorbed by erythrocytes and enzymatically reduced to hydrogen selenide. Hydrogen selenide serves as the central selenium pool for excretion and for specific incorporation in selenoproteins. In this reduced form, selenium is bound to plasma proteins present in the liver and other organs. The plasmatic secondary transport from the liver to the glutathionperoxidase-synthesizing target tissues takes place in the form of selenocystein (selenoprotein P). The further metabolic process of the selenoprotein biosynthesis is currently known only in prokaryotes. Selenocystein is then specifically incorporated into the peptide chains of the glutathionperoxidase.

Excess of hydrogen selenide is transformed into methylated metabolites (methyl selenol, dimethylselenide and trimethylselenonium ion) prior to being excreted into urine and/or exhaled.

The total quantity of selenium in the human body is between 3 mg and 20 mg. In human, selenium is excreted in feces, urine or lung, depending on the administered dosage. Selenium is primarily renally excreted in the form of trimethylselenonium ion. The excretion depends on the selenium status.

The selenium excretion after oral intake takes place in three phases with a terminal half-life of 65 to 116 days.

PHARMACEUTICAL PARTICULARS

LIST OF EXCIPIENTS

Di-Calcium Phosphate, Magnesium Stearate, Mannitol, Microcrystalline Cellulose, Polyvinylpyrrolidone, Silicon Dioxide, Stearic Acid

INCOMPATIBILITIES

Selenium is generally incompatible with high concentration of ascorbic acid (reduction of selenite to elemental selenium which is not soluble and unavailable as a nutritional source of selenium).

SHELF LIFE

2 years

SPECIAL PRECAUTIONS FOR STORAGE

Store at or below 25 °C | KEEP OUT OF REACH OF CHILDREN.

NATURE AND CONTENTS OF CONTAINER

HERBIEVITE - SELENIUM are packed in white HDPE containers with white cap, containing a desiccant in pack sizes of 30 tablets and 100 tablets.

SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING

No special requirements.

HOLDER OF CERTIFICATE OF REGISTRATION

Contego Pharmaceuticals (Pty) Ltd
250 Nadine Street
Robertville, Roodepoort
Gauteng, South Africa
+27 87 150 7529

REGISTRATION NUMBER

To be allocated.

DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

To be allocated.

