

SCHEDULING STATUS

Not scheduled

HERBIEVITE CONCENTR8 KIDS (softgel)

Each chewable soft capsule contains:

- Fish Oil 200 mg
- Vitamin C (Ascorbic Acid) 30 mg
- Vitamin E (D-α-Tocopherol Acetate) 1,5 mg
- Vitamin A 40 µg
- Vitamin D3 Oil 2,5 µg

Western Herbal Complementary Medicine and Health Supplement.

HERBIEVITE CONCENTR8 KIDS 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.

Read all of this leaflet carefully because it contains important information for you.

HERBIEVITE CONCENTR8 KIDS is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use HERBIEVITE CONCENTR8 KIDS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share HERBIEVITE CONCENTR8 KIDS with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What HERBIEVITE CONCENTR8 KIDS is and what it is used for.
2. What you need to know before you take HERBIEVITE CONCENTR8 KIDS.
3. How to take HERBIEVITE CONCENTR8 KIDS.
4. Possible side effects.
5. How to store HERBIEVITE CONCENTR8 KIDS.
6. Contents of the pack and other information.

1. What HERBIEVITE CONCENTR8 KIDS is and what it is used for

HERBIEVITE CONCENTR8 KIDS is a Western Herbal Complementary and Health Supplement
HERBIEVITE CONCENTR8 KIDS plays a factor in the maintenance of good health.
HERBIEVITE CONCENTR8 KIDS is a multi-vitamin/fish oil supplement.

2. What you need to know before you take HERBIEVITE - SELENIUM

Do not take HERBIEVITE CONCENTR8 KIDS:

- If you are allergic (hypersensitive) to fish oil, vitamin A, vitamin C, vitamin D3, vitamin E or any of the other ingredients in the tablets (these are listed in section 6. Contents of the pack and other information).
- If you have high levels of calcium in your blood (hypercalcaemia) or urine (hypercalciuria).
- If you are suffering from kidney failure, have kidney stones (renal calculi) or have a tendency to form kidney stones.
- If you have high levels of vitamin D in your blood (hypervitaminosis D).
- If you have a Vitamin K deficiency.
- If you have an eye condition in which the retina is damaged (retinitis pigmentosa).
- If you have a bleeding disorder.
- If you have a history of previous heart attacks or strokes.
- If you have head and neck cancer.
- If you have a liver disease.

Warnings and precautions

Take special care with HERBIEVITE CONCENTR8 KIDS:

- If you are allergic to fish.
- If you have bipolar disorder as fish oil might increase some of the symptoms.
- If you have scarring due to liver disease as fish oil might increase the risk of bleeding.
- If you have depression as fish oil might increase some of the symptoms.
- If you are being treated with blood pressure-lowering medication as fish oil can lower blood pressure and might cause blood pressure to drop too low.
- If you have a weak immune system high doses of fish oil can lower the body's immune system response.
- If you have any of the following conditions: celiac disease, short gut syndrome, jaundice, cystic fibrosis, pancreatic disease, and cirrhosis of the liver, are not able to absorb vitamin A properly.
- If you have a type of high cholesterol called "Type V hyperlipoproteinemia" - this condition might increase the chance of vitamin A poisoning.
- If you have intestinal infections such as hookworms as this can reduce how much vitamin A the body absorbs.
- If you have iron deficiency as this might affect the body's ability to breakdown and use vitamin A.
- If you have a liver disease as too much vitamin A might make it worse.
- If you are a diabetic or are to undergo any blood or urine tests as vitamin C can interfere with some blood and urine tests.
- If you are a regular smoker.
- If you have kidney failure, as vitamin C enhances aluminium absorption (present in antacids) which may reach toxic levels.
- If you have a hereditary disease associated with an excess of iron in the body.
- If you are at risk of recurring formation of kidney stones. In case of susceptibility to kidney stones, there is the risk of the formation of kidney stones (calcium oxalate calculi) due to the intake of high doses of vitamin C.
- If you suffer from heart disease or narrowing of the arteries.
- If you suffer from sarcoidosis (a multisystem chronic inflammatory condition which can affect your lungs, heart and kidneys), then there is a risk of increased conversion of vitamin D into its active form.
- If you are taking medicines containing vitamin D, or eating foods or drinking milk enriched with vitamin D.

- Your doctor may want you to have regular blood tests to check the amount of calcium in your blood.
- When taking supplements containing vitamin E or other antioxidant vitamins avoid taking them immediately before and following angioplasty without the supervision of a health care professional.
- If you have a bleeding disorder, avoid taking vitamin E supplements.
- If you have a liver disease called non-alcoholic fatty liver disease (NAFLD), taking vitamin E for 2 years or more can worsen insulin resistance.
- If you are going to have surgery stop taking vitamin E at least 2 weeks before a scheduled surgery.
- Vitamin E might worsen clotting problems in people whose levels of vitamin K are too low.

Other medicines and HERBIEVITE CONCENTR8 KIDS

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines). You must tell your doctor or pharmacist if you are taking any of the following medicines:

- Birth control pills such as ethinyl estradiol and levonorgestrel (Triphasil), ethinyl estradiol and norethindrone (Or-tho-Novum 1/35, Ortho-Novum 7/7/7), and others.
- Medications for high blood pressure such as captopril (Capoten), enalapril (Vasotec), losartan (Cozaar), valsartan (Diovan), diltiazem (Cardizem), Amlodipine (Norvasc), hydrochlorothiazide (HydroDiuril), furosemide (Lasix), and many others.
- Medications that slow blood clotting such as aspirin, clopidogrel (Plavix), diclofenac (Voltaren, Cataflam, others), ibupro-fen (Advil, Motrin, others), naproxen (Anaprox, Naprosyn, others), dalteparin (Fragmin), enoxaparin (Lovenox), heparin, warfarin (Coumadin), and others.
- Synthetic retinoids such as acitretin, isotretinoin and tretinoin.
- Vitamin A can interact with some antibiotics. Some of these antibiotics include demeclocycline (Declomycin), minocycline (Minocin), and tetracycline (Achromycin).
- Medications that can harm the liver include acetaminophen (Tylenol and others), amiodarone (Cordarone), carbamazepine (Tegretol), isoniazid (INH), methotrexate (Rheumatrex), methyl dopa (Aldomet), fluconazole (Diflucan), itraconazole (Sporanox), erythromycin (Erythrocin, Ilosone, others), phenytoin (Dilantin), lovastatin (Mevacor), pravastatin (Pravachol), simvastatin (Zocor), and many others.
- Warfarin (Coumadin) is used to slow blood clotting. Large amounts of Vitamin A can also slow blood clotting. Taking vitamin A along with warfarin (Coumadin) can increase the chances of bruising and bleeding. Be sure to have your blood checked regularly. The dose of your warfarin (Coumadin) might need to be changed.
- Vitamin C in a dosage of 1 g daily increases the absorption of oral contraceptives (oestrogens).
- Vitamin C increases the renal excretion of amphetamine.
- High doses of vitamin C taken together with iron supplements may cause an iron overload.
- High doses of vitamin C taken together with aluminium (e.g. antacids such as aluminium hydroxide, magaldrate) may cause increased absorption of aluminium into the body.
- Vitamin C is an antioxidant and might decrease the effectiveness of some medications used for cancers.
- Taking large doses of vitamin C might reduce how much of some medications used for HIV/AIDS stays in the body. This could decrease the effectiveness of some medications used for HIV/AIDS. Some of these medications used for HIV/AIDS include amprenavir (Agenerase), nelfinavir (Viracept), ritonavir (Norvir), and saquinavir (Fortovase, Invirase).
- Co-administration with amygdalin (a complementary medicine - vitamin B17) can cause cyanide toxicity.
- Vitamin C can decrease the therapeutic effect of blood thinning medication, such as warfarin and the antipsychotic drugs phenothiazines such as fluphenazine.
- Taking vitamin C, beta-carotene, selenium, and vitamin E together might decrease the effectiveness of some medications used for lowering cholesterol.
- Large amounts of vitamin C can decrease how quickly the body breaks down acetaminophen.
- Large amounts of vitamin C might decrease the breakdown of aspirin.
- Taking nicardipine (Cardene) or nifedipine (Adalat, Procardia) along with vitamin C might decrease how much vitamin C is taken in by cells.
- Taking vitamin C along with salsalate (Disalcid) might cause too much salsalate (Disalcid).
- Medicines for epilepsy such as barbiturates or other anti-convulsants (e.g. carbamazepine, phenobarbital, phenytoin, primidone).
- Other vitamin D containing medicines including multi-vitamins.
- Medicines to control the rate of your heart beat (e.g. digoxin, digitoxin).
- Diuretics (water tablets) such as Bendroflumethiazide.
- Calcium supplements.
- Medicines to treat tuberculosis e.g. rifampicin, isoniazid.
- Medicines leading to fat malabsorption e.g. orlistat, cholestyramine, liquid paraffin.
- Medicines to treat fungal infections i.e. ketoconazole, itraconazole.
- Actinomycin (a medicine used to treat some forms of cancer) as it may interfere with the metabolism of vitamin D.
- Glucocorticosteroids (steroid hormones such as hydrocortisone or prednisolone).
- Taking large amounts of vitamin E along with cyclosporine (Neoral, Sandimmune) might increase how much cyclosporine (Neoral, Sandimmune) the body absorbs.
- Medications changed by the liver include lovastatin (Mevacor), ketoconazole (Nizoral), itraconazole (Sporanox), fexofenadine (Allegra), triazolam (Halcion), and many others.
- Medications that slow blood clotting include aspirin, clopidogrel (Plavix), diclofenac (Voltaren, Cataflam, others), ibupro-fen (Advil, Motrin, others), naproxen (Anaprox, Naprosyn, others), dalteparin (Fragmin), enoxaparin (Lovenox), heparin, warfarin (Coumadin), and others.
- Medications used for lowering cholesterol include atorvastatin (Lipitor), fluvastatin (Lescol), lovastatin (Mevacor), and pravastatin (Pravachol).

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine. Vitamin A can cause birth defects. It is especially important for pregnant women to monitor their intake of vitamin A from all sources during the first three months of pregnancy. If you require extra vitamin D do not take it without medical supervision because too much vitamin D may harm your baby.

Driving and using machines

HERBIEVITE CONCENTR8 KIDS should not affect your ability to drive or operate machinery. It is not always possible to predict to what extent HERBIEVITE CONCENTR8 KIDS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which HERBIEVITE CONCENTR8 KIDS affect them.

3. How to Take HERBIEVITE CONCENTR8 KIDS

Do not share medicines prescribed for you with any other person. Always take HERBIEVITE CONCENTR8 KIDS exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure. **The usual dose is:** Take 6 chewable soft gel capsules for persons 18 years and older. If you take more HERBIEVITE CONCENTR8 KIDS than you should In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control center.

Large doses of vitamin C may cause diarrhoea and the formation of kidney stones. Symptomatic treatment may be required. Large doses of vitamin C may cause kidney failure if you suffer from hereditary disorders of red blood cells (e. g. Glucose-6-Phosphate dehydrogenase deficiency) You may need to have your stomach pumped if ingestion is recent otherwise general supportive measure should be employed as required.

Some symptoms of taking too much vitamin D include nausea, vomiting, diarrhoea often in the early stages and later constipation, anorexia, fatigue, headache, muscle and joint pain, muscle weakness, polydipsia, polyuria formation of renal calculi, nephrocalcinosis, kidney failure, calcification of soft tissues, changes in ECG measurements, arrhythmias and pancreatitis.

Relatively large amounts of vitamin E usually cause no harm but occasionally muscle weakness, fatigue, nausea, and diarrhea occur. The most significant risk is bleeding, mainly with doses > 1000 mg a day.

If you forget to take HERBIEVITE CONCENTR8 KIDS If you forget to take your tablets, take them as soon as possible. Then take the next dose at the correct time, in accordance with the instructions given to you by your doctor. However, if it is almost time to take the next dose, do not take the dose you have missed; just take the next dose as normal. Do not take a double dose to make up for a forgotten dose.

4. Possible Side Effects

HERBIEVITE CONCENTR8 KIDS can have side effects. Not all side effects reported for HERBIEVITE CONCENTR8 KIDS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking HERBIEVITE CONCENTR8 KIDS, please consult your doctor, pharmacist or other health care professional for advice.

Fish oil can cause side effects including:

- belching.
- bad breath.
- heartburn.
- nausea.
- loose stools.
- rash.
- and nosebleeds.

Long-term use of large amounts of vitamin A might cause serious side effects including:

- fatigue.
- irritability.
- mental changes.
- anorexia.
- stomach discomfort.
- nausea.
- vomiting.
- mild fever.
- excessive sweating.
- and many other side effects.

Vitamin A might be unsafe for children when taken high doses. When amounts greater than those recommended are taken, side effects can include:

- irritability.
- sleepiness.
- vomiting.
- diarrhea.
- loss of consciousness.
- headache.
- vision problems.
- peeling skin.
- increased risk of pneumonia and diarrhea and other problems.

Tell your doctor if you notice any of the following:

- Diarrhoea, Stomach cramps, nausea (feeling sick), vomiting (being sick).
- Flushing or redness of the skin.
- Haemolytic anaemia (where the body's immune system attacks its own red blood cells), signs may include fatigue and paleness.

- Diuretic effect (increased urine flow) due to increased intake of vitamin C over prolonged period. This may lead to deficiency if the amount of vitamin C taken is reduced or stopped rapidly.
- Headache.

Side effects with Cholecalciferol Capsules may include:

Uncommon side effects

- too much calcium in your blood (hypercalcaemia). You may feel or be sick, lose your appetite, have constipation, stomach ache, feel very thirsty, have muscle weakness, drowsiness or confusion.
- too much calcium in your urine (hypercalciuria).

Rare side effects

- Skin rash
- Itching
- Raised itchy rash (hives)

Vitamin E side effects can include:

- nausea
- diarrhea
- stomach cramps
- fatigue
- weakness
- headache
- blurred vision
- rash
- and bruising and bleeding

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse.

You can also report side effects 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, South Africa

By reporting side effects, you can help provide more information on the safety of HERBIEVITE CONCENTR8 KIDS.

5. How to store HERBIEVITE CONCENTR8 KIDS

KEEP OUT OF REACH OF CHILDREN.

Store at or below 25 °C. Protect from heat and light.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What HERBIEVITE CONCENTR8 KIDS contains

Active Substance:

Each chewable soft capsule contains:

Fish Oil 200 mg

Vitamin C (Ascorbic Acid) 30 mg

Vitamin E (D-a-Tocopherol Acetate) 1,5 mg

Vitamin A 40 µg

Vitamin D3 Oil 2,5 µg

The other ingredients are:

Mannitol 180mg / per softgel (E421)

Gelatin (E441)

Glycerol (E422)

Soyabean oil

Purified Water

Mono- and diglycerides of fatty acids (E471)

Lecithin (E322)

Flavouring

Titanium dioxide (E171)

Aspartame 2.35mg / per softgel(E962)

Citric acid (E300)

Acesulfame K1.39mg / per softgel (E950)

Rosemary Extract (E392)

What HERBIEVITE CONCENTR8 KIDS looks like and content of the pack

HERBIEVITE CONCENTR8 KIDS is an off-white, opaque softgel.

HERBIEVITE CONCENTR8 KIDS are packed in white HDPE containers with white cap, containing a desiccant in pack size of 30 chewable softgel capsules.

Holder of Certificate of Registration

Contego Pharmaceuticals (Pty) Ltd

250 Nadine Street

Robertville, Roodepoort

South Africa

This leaflet was last revised in

To be allocated.

Registration Number

To be allocated.