

PACKAGE INSERT

SCHEDULING STATUS

To be assigned

PROPRIETARY NAME AND DOSAGE FORM

Opti-CAL Tablets

COMPOSITION

Opti-CAL is comprised of 1 Component:

<i>Component 1:</i>	
Each White Calcium & Collagen Tablet contains:	
Calcium (derived from Calcium Carbonate)	500 mg
Collagen (as Collagen Hydrolysed Type 1)	150 mg
Copper (derived from Copper Sulphate)	1 mg
Magnesium (derived from Magnesium Oxide)	150 mg
Manganese (derived from Manganese Sulphate)	3 mg
Potassium (derived from Potassium Phosphate Dibasic)	20 mg
Selenium (derived from Selenium Amino Acid Chelate)	30 µg
Silicon (derived from Silica Amino Acid Chelate)	1 mg
Vitamin D3 (as Cholecalciferol)	1 000 IU
Vitamin K2 (as Mena Q7)	45 µg
Zinc (derived from Zinc Oxide)	15 mg
Excipients: Flexicoat® white, magnesium stearate (vegetable), maize starch, povidone, shellac, silicon dioxide	

PHARMACOLOGICAL CLASSIFICATION

D: 32.2 (Other): Health Supplement

PHARMACOLOGICAL ACTION

Pharmacodynamics:

Calcium: Calcium plays a structural role in bones and teeth and is essential for cellular structure, blood clotting, muscle contraction, nerve transmission, enzyme activation and hormone function.

Collagen (hydrolysed Type 1): Hydrolysed collagen is a source of essential and non-essential amino acids which are involved in protein and collagen synthesis.

Copper: Copper functions as an essential component of several enzymes (e.g. superoxide dismutase) and other proteins. It plays a role in bone formation and mineralisation, and in the integrity of the connective tissue of the cardiovascular system. Copper has pro-oxidant effects in vitro but antioxidant effects in vivo; there is accumulating evidence that adequate copper is required to maintain antioxidant effects within the body.

Magnesium: Magnesium is an essential cofactor for enzymes requiring adenosine triphosphate (ATP) (these are involved in glycolysis, fatty acid oxidation and amino acid metabolism). It is also required for the synthesis of ribonucleic acid (RNA) and replication of deoxyribonucleic acid (DNA); neuromuscular transmission; and calcium metabolism.

Manganese: Manganese activates several enzymes, including hydroxylases, kinases, decarboxylases and transferases. It is also a constituent of several metallo-enzymes, such as arginase, pyruvate carboxylase, and also superoxide dismutase, which protects cells from free radical attack. It may have a role in the regulation of glucose homeostasis and in calcium mobilisation.

Potassium: Potassium is the principal intracellular cation, and is fundamental to the regulation of acid-base and water balance. It contributes to transmission of nerve impulses, control of skeletal muscle contractility and maintenance of blood pressure.

Selenium: Selenium functions as an integral part of the enzyme glutathione peroxidase and other seleno-proteins. Glutathione peroxidase prevents the generation of oxygen free radicals that cause the destruction of polyunsaturated fatty acids in cell membranes.

Silicon: Silicon is involved in the formation of bones and connective tissues.

Vitamin D: Vitamin D is essential for promoting the absorption and utilisation of calcium and phosphorus and normal calcification of the skeleton. Along with parathyroid hormone (PTH) and calcitonin, it regulates serum calcium concentration by altering serum calcium and phosphate blood levels as needed, and mobilising calcium from bone. It maintains neuromuscular function and various other cellular processes, including the immune system and insulin production.

Vitamin K2: Vitamin K is responsible for the carboxylation of the bone protein, osteocalcin, to its active form. Osteocalcin regulates the function of calcium in bone turnover and mineralisation.

Zinc: Zinc is an essential component of over 200 enzymes. It plays an important role in the metabolism of proteins, carbohydrates, lipids and nucleic acids. It is a cofactor in a range of biochemical processes, including the synthesis of DNA, RNA and protein.

INDICATIONS

Helps build, strengthen and maintain healthy bones.

CONTRAINDICATIONS

Hypersensitivity to any of the ingredients, including excipients.

Not for use in children and adolescents below the age of 18 years.

Opti-CAL should not be used by persons suffering from:

- conditions associated with hypercalcaemia and hypercalcuria, and in renal impairment (chronic);
- renal osteodystrophy with hyperphosphataemia (risk of metastatic calcification);
- Wilson’s disease (the disorder may be exacerbated);
- hepatic and biliary disease.

WARNINGS AND SPECIAL PRECAUTIONS

Take 2 hours before or after taking other medications.

Consult your healthcare professional if:

- you are taking blood thinners;
- symptoms worsen;
- you are following a low protein diet.

Use for a minimum of 1 month to see beneficial results.

INTERACTIONS

Bisphosphonates: calcium may reduce absorption of etidronate.

4-Quinolones: calcium and magnesium may reduce absorption of 4-quinolones.

Tamoxifen: calcium supplements may increase the risk of hypercalcaemia (a rare side-effect of tamoxifen therapy).

Tetracyclines: calcium and magnesium may reduce absorption of tetracyclines.

Iron: calcium carbonate or calcium phosphate may reduce absorption of iron.

Zinc: calcium may reduce absorption of zinc.

Calcitonin: effect of calcitonin may be antagonised by vitamin D.

Digoxin: caution because hypercalcaemia caused by vitamin D may potentiate effects of digoxin, resulting in cardiac arrhythmias.

Thiazide diuretics: vitamin D may increase risk of hypercalcaemia.

Vitamin D analogues (alfacalcidol, calcitriol, dihydrotachysterol): increased risk of toxicity with vitamin D supplements.

PREGNANCY AND LACTATION

Safety during pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE

For oral use.

Evening: Take one White Calcium & Collagen Tablet with Dinner.

Take 2 hours before or after taking other medications.

SIDE EFFECTS

May cause mild gastrointestinal disturbances e.g. nausea, diarrhoea, constipation, indigestion, bloating and flatulence.

Zinc supplementation may cause a copper deficiency.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Vitamin D could (in exceptional circumstances) cause toxicity; the margin of safety is very narrow.

There is a wide variation in tolerance to vitamin D.

Excessive intake leads to hypercalcaemia and its associated effects. These include apathy, anorexia, constipation, diarrhoea, dry mouth, fatigue, headache, nausea and vomiting, thirst and weakness. Later symptoms are often associated with calcification of soft tissues and include bone pain, cardiac arrhythmias, hypertension, renal damage (increased urinary frequency, decreased urinary concentrating ability; nocturia, proteinuria), psychosis (rare) and weight loss. If an overdose is suspected, the medicine should be stopped immediately.

IDENTIFICATION

Component 1: White Oval Film-coated Tablet.

PRESENTATION

A cardboard carton containing a blister strip of 30 White Calcium & Collagen Tablets.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Protect from light and moisture.

Keep the blister strips in the outer carton.

KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBER

To be assigned

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

AnaStellar Brands (Pty) Ltd
Boskruin Business Park, Unit 15, North Wing, Ground Floor, Bosbok Road, Randpark Ridge, 2169, Gauteng, Republic of South Africa
+27 (0)11 792 4601

DATE OF PUBLICATION OF THE PACKAGE INSERT

July 2016

This medicine has not been evaluated by the Medicines Control Council. This medicine is not intended to diagnose, treat, cure or prevent any disease.

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

To be assigned

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Opti-CAL Tablets

Read all of this leaflet carefully before you start taking Opti-CAL

Opti-CAL is available without a doctor’s prescription, for you to treat a mild condition. Nevertheless you still need to use Opti-CAL carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Opti-CAL with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

WHAT FLEXI-CAL CONTAINS

Opti-CAL is comprised of 1 Component:

Component 1:

Each White Calcium & Collagen Tablet contains:	
Calcium (derived from Calcium Carbonate)	500 mg
Collagen (as Collagen Hydrolysed Type 1)	150 mg
Copper (derived from Copper Sulphate)	1 mg
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Vitamin D3 (as Cholecalciferol)	1 000 IU
Vitamin K2 (as Mena Q7)	45 µg
Zinc (derived from Zinc Oxide)	15 mg

The other ingredients are Flexicoat® white, magnesium stearate (vegetable), maize starch, povidone, shellac and silicon dioxide.

WHAT Opti-CAL IS USED FOR

Helps build, strengthen and maintain healthy bones.

BEFORE YOU TAKE Opti-CAL

Do not take Opti-CAL if:

- Hypersensitive (allergic) to any of the ingredients of Opti-CAL.
- You are younger than 18 years old.
- You suffer from chronic kidney disease or if you have high levels of calcium in either your blood or urine.
- You suffer from renal osteodystrophy with hyperphosphataemia (a bone disease caused by incorrect functioning of the kidneys).

Take special care with Opti-CAL:

Take Opti-CAL 2 hours before or after taking any medication.

Consult your healthcare professional if:

- you are taking blood thinners;
- your symptoms worsen;
- you are following a low protein diet.

You should use Opti-CAL for at least 1 month before you see beneficial results.

Taking Opti-CAL with food and drink: Opti-CAL should be taken with food.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Taking other medicines with Opti-CAL:

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

This includes complementary or traditional medicines.

Bisphosphonates (used in the treatment of osteoporosis): calcium may reduce absorption of etidronate.

4-Quinolones (a group of antibiotics): calcium and magnesium may reduce absorption of 4-quinolones.

Tamoxifen (used in the prevention and treatment of breast cancer): calcium supplements may increase the risk of hypercalcaemia (high levels of calcium in the blood).

Tetracyclines (a type of antibiotic): calcium and magnesium may reduce absorption of tetracyclines.

Iron: calcium carbonate or calcium phosphate may reduce absorption of iron.

Zinc: calcium may reduce absorption of zinc.

Calcitonin (a hormone): vitamin D may work against the effect of calcitonin.

Digoxin (a medicine used to treat heart failure): high calcium levels in the blood caused by vitamin D may increase the effects of digoxin, resulting in cardiac arrhythmias (abnormal heart rhythm).

Thiazide diuretics (a medicine used to treat high blood pressure and water retention/swelling): vitamin D may increase the risk of hypercalcaemia (high levels of calcium in the blood).

Vitamin D analogues (alfacalcidol, calcitriol, dihydrotachysterol): increased risk of toxicity with vitamin D supplements.

HOW TO TAKE Opti-CAL

Do not share medicines with any other person.

You should check with your doctor or pharmacist if you are unsure on how to use Opti-CAL. The usual dose is one white calcium & collagen tablet in the evening with dinner. Take 2 hours before or after taking other medications.

If you take more Opti-CAL than you should:

In the event of an overdose, consult your doctor or pharmacist.

If neither is available, contact the nearest hospital or poison control centre.

If you missed a dose of Opti-CAL:

Do not take a double dose to make up for a forgotten individual dose.

POSSIBLE SIDE EFFECTS

Opti-CAL can have side effects.

Not all side effects reported for Opti-CAL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice. You may (in exceptional circumstances) experience nausea, diarrhoea, constipation, indigestion, bloating and flatulence while taking Opti-CAL. Zinc supplementation may cause a copper deficiency. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF OPTI-CAL

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light and moisture.

Keep the blister strips in the outer carton.

Return all unused medicine to your pharmacist.

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

PRESENTATION OF OPTI-CAL

A cardboard carton containing a blister strip of 30 White Calcium & Collagen Tablets.

IDENTIFICATION OF OPTI-CAL

Component 1: White Oval Film-coated Tablet.

REGISTRATION NUMBER:

To be assigned

NAME AND ADDRESS OF REGISTRATION HOLDER

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