

PATIENT INFORMATION LEAFLET
RADICAL® TABLETS

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use. Complementary Medicine: Health supplement. Health Supplements are intended only to complement health or supplement the diet.

SCHEDULING STATUS
[S0](#)

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM
RADICAL® TABLETS (tablets)

Read all of this leaflet carefully because it contains important information for you. RADICAL® TABLETS is available without a doctor’s prescription, as a supplement. Nevertheless, you still need to use RADICAL® TABLETS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share RADICAL® TABLETS 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, or if you notice any side effect not listed in this leaflet.

1. WHAT RADICAL® TABLETS CONTAINS
Each tablet contains:

Active Ingredients	Elemental quantity per tablet	% NRV#
K2D3™ complex	70,0 µg	
Providing		
Vitamin D3 (<i>Cholecalciferol</i>)	1000 IU (25 µg)	167 %
Vitamin K2 (<i>Menaquinone</i>)	45 µg	38 %
Calcium (<i>as Calcium carbonate</i>)	600,0 mg	46 %
Magnesium (<i>as Magnesium oxide</i>)	100,0 mg	24 %
Copper (<i>as copper chelate</i>)	0,5 mg	56 %
Manganese (<i>as manganese chelate</i>)	0,5 mg	22 %
Zinc (<i>as Zinc gluconate</i>)	4,35 mg	40 %

Nutrient Reference Values for adults and children 4 years and older.

The other ingredients are: colloidal silicon dioxide, magnesium stearate, sodium starch glycolate, and stearic acid.
RADICAL® TABLETS are sugar free.
Contains Sweeteners: mannitol 80 mg/tablet; sorbitol 45,69 mg/tablet.

2. WHAT RADICAL® TABLETS IS USED FOR
RADICAL® TABLETS helps maintain healthy bones and teeth. K2D3™ complex supports optimal calcium absorption. RADICAL® TABLETS helps to lower your risk of bone mineral loss and osteoporosis – where the bones become brittle and fragile. For a diagnosis, consult a medical practitioner.

3. BEFORE YOU TAKE RADICAL® TABLETS
Do not take RADICAL® TABLETS:

- If you are hypersensitive (allergic) to calcium, vitamin D or any of the ingredients of RADICAL® TABLETS (see WHAT RADICAL® TABLETS CONTAINS),
- if you have severe kidney problems or kidney stones,
- if you have excessive amounts of calcium in the blood or in the urine,
- if you have excessive amounts of vitamin D in the blood,
- if you are taking anticoagulants (blood thinning medication) such as warfarin you must not take this supplement,
- if you have porphyria.

Ask your doctor or pharmacist if you are not sure about any of the above.

Take special care with RADICAL® TABLETS:
You must see a doctor if you have one (1) or more of the following:

- If you have problems with your kidneys for example kidney stones, or heart disease or if you have been told that you have an increased risk of damage to your organs,
- if you are taking any other medicines containing vitamin D or calcium. This may increase the level of calcium in your blood above safe levels which may cause side effects,
- if you have sarcoidosis (an immune system disorder which may cause increased levels of vitamin D in the body).

Taking RADICAL®TABLETS with food and drink:
RADICAL® TABLETS should be taken apart from certain foods such as bran as it may reduce the absorption of this health supplement. Certain foods e.g. those containing oxalic acid (e.g. spinach and rhubarb), phosphate (e.g. bran) or phytic acid (e.g. whole cereals) may reduce the absorption of RADICAL® TABLETS.

Pregnancy and Breastfeeding:
RADICAL® TABLETS is safe for use during pregnancy and breastfeeding but ask your healthcare professional for advice.

Driving and using machinery:
No studies on the effect of RADICAL® TABLETS on the ability to drive or operate machinery were performed. It is unlikely that RADICAL® TABLETS would affect your ability to drive or use machinery. Patients should not drive or operate machinery until it is established that their ability to perform such activities has not been affected.

Important information about some of the ingredients of RADICAL® TABLETS:
RADICAL® TABLETS are sugar free. RADICAL® TABLETS contains mannitol (80mg / tablet) and sorbitol (45,69mg / tablet). If you have been told that you have an intolerance to some sugars, you should not take RADICAL® TABLETS.

Taking other medicines with RADICAL® TABLETS:
Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines). The use of RADICAL® TABLETS with these medicines may cause undesired interactions. Please consult your doctor, pharmacist or other healthcare professional.
Do not take RADICAL® TABLETS in combination with medicines such as:

- Thiazide diuretics (used in treatment of high blood pressure or oedema).
- Tetracycline’s (a type of antibiotic), and some fluoroquinolones (antibiotics), should be taken at least 2 hours before or 4-6 hours after intake of RADICAL® TABLETS. Calcium carbonate may interfere with the absorption of these antibiotic preparations if taken

- at the same time.
- Corticosteroids (steroidal anti-inflammatory agents) decreases absorption of calcium,
- Cardiac glycosides, such as digitalis (certain heart medication).
- Bisphosphonates (agents which slow down bone loss or density, used for Osteoporosis), fluoride and iron, doses should be separated by three hours.
- Calcium can reduce the effect of levothyroxine (used to treat thyroid deficiency). For this reason, levothyroxine should be taken at least four hours before or four hours after RADICAL® TABLETS.
- Calcium salts may decrease the absorption of iron, zinc and strontium ranelate. Thus, these preparations should be taken at least two hours before or after this supplement
- Orlistat (used to treat obesity) may disturb the absorption of fat-soluble vitamins e.g. vitamin D3.
- Anticoagulants: Vitamin K decreases the effectiveness of anticoagulants. Individuals taking anticoagulants must not take this medication.
- Some medicines to treat epilepsy (such as carbamazepine, phenobarbital, phenytoin and primidone), rifampicin, isoniazid and corticosteroids may reduce the effectiveness of vitamin D3.

4. HOW TO TAKE RADICAL® ADULT TABLETS
Do not share your medicines with any other person. Do not exceed the recommended daily dosage. Always take RADICAL®TABLETS exactly as indicated or as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is:
Adults and children 12 years and older:
One (1) tablet in the evening, after a meal with, a glass of water.
Children under 12:
RADICAL® TABLETS must not be given to children under 12 years old.

If you take more RADICAL® TABLETS than you should:
In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take / missed a dose of RADICAL® TABLETS:
Take your missed dose when you remember. Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with RADICAL® TABLETS is stopped:
When you are taking the dose as indicated it is unlikely that there should be withdrawal effects when you stop using this medication, however, always tell your doctor or pharmacist before stopping the use of RADICAL® TABLETS.

5. POSSIBLE SIDE EFFECTS
RADICAL® TABLETS may have side effects such as:
Hypersensitivity reactions (with unknown frequency).
If you experience the following symptoms, you should immediately contact a doctor or go to the casualty department at your nearest hospital:

- swelling of the face, tongue, lips (angioedema) or swelling of the throat (laryngeal oedema).

Frequent:

- constipation
- winds

Less frequent:

- abdominal discomfort
- diarrhea
- nausea
- formation of kidney stones

Should your general health worsen, or if you experience any undesired effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice. Not all side effects are included in this leaflet. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF RADICAL® TABLETS
Store at or below 25 °C. Protect from light and moisture. Keep the container tightly closed in order to protect from moisture. Store in original packaging until required for use. Do not store in a bathroom. Do not use after the expiry date stated on the label and carton. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets). Return all unused medicine to your pharmacist.
STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

7. PRESENTATION OF RADICAL® ADULT TABLETS
White container with red cap, containing 30 or 60 tablets, and a leaflet packed in an outer carton.

8. IDENTIFICATION OF RADICAL® ADULT TABLETS
White oblong tablet.

9. REGISTRATION NUMBER
To be allocated.

10. NAME AND ADDRESS OF REGISTRATION HOLDER
Nativa (Pty) Ltd
260 Cradock Avenue, Lyttelton, Centurion, 0157, Gauteng, South Africa
Tel: +27 (0) 12 664 7110
Customer care line: 0860 628 482
Email: health@nativa.co.za
Website: www.nativa.co.za

11. DATE OF PUBLICATION
To be allocated.

12. DATE OF REGISTRATION
To be allocated.

13. CATEGORY AND CLASS
D.34.12 Complementary Medicines: Health Supplements – Multiple substance formulation.

The RADICAL® TABLETS professional information may be obtained from the Nativa website (www.nativa.co.za).