PROFESSIONAL INFORMATION FOR CORAL CALCIUM

SCHEDULING STATUS:
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PROPRIETARY NAME AND DOSAGE FORM:
CORAL CALCIUM capsules

COMPOSITION:
Active Ingredients:
Each capsule contains:
Coral Calcium powder…… 500 mg
Vitamin D ……... 150 i.u.
Sugar free.

Inactive Ingredients:
Magnesium stearate, silicon dioxide, talc.

CATEGORY AND CLASS:
D 34.12 Multiple substance formulation

PHARMACOLOGICAL ACTION:
Coral Calcium powder is a combination of naturally occurring Calcium and Magnesium with added Vitamin D.
Calcium helps in the development and maintenance of bones and teeth.
Vitamin D is a fat-soluble vitamin that helps in the absorption and use of Calcium.
Cholecalciferol (Vitamin D) is biologically inert and requires hydroxylation in the body to form the active metabolite calcitriol. Vitamin D enhances the efficiency of the intestinal absorption of Calcium, primarily in the duodenum and jejunum.

INDICATIONS:
CORAL CALCIUM is a Calcium and Magnesium supplement with added Vitamin D.
Calcium intake, when combined with sufficient Vitamin D, a healthy diet, and regular exercise, may reduce the risk of developing osteoporosis.

CONTRAINDICATIONS:
Hypersensitivity to any of the ingredients (see **"COMPOSITION"**).
Pregnancy and lactation (see **"HUMAN REPRODUCTION"**).

WARNINGS AND SPECIAL PRECAUTIONS:
Warnings:
Please consult a healthcare professional if you have any diagnosed condition or are taking any other medication.
Do not exceed the recommended dosage.
May contain trace amounts of Iodine.
Do not take concurrently with other medications (see **"INTERACTIONS"** and **"DOSAGE AND DIRECTIONS"**).
CORAL CALCIUM is not intended for use in children under the age of 9 years.

Special precautions:
Patients on any other medicine should discuss the use of **CORAL CALCIUM** with their healthcare professional before using **CORAL CALCIUM** (see **"INTERACTIONS"** and **"DOSAGE AND DIRECTIONS"**).
Patients with renal disorders should consult their healthcare professional prior to using **CORAL CALCIUM.**

Effects on ability to drive and use machines:
CORAL CALCIUM should not affect your ability to drive or use machines that require your attention. However, this has not been tested and you should not drive or use machines until you know how **CORAL CALCIUM** affects you.

INTERACTIONS:
Please consult a healthcare professional if you have any diagnosed condition or are taking any other medication, this includes complementary or traditional medicines (see **"WARNINGS AND SPECIAL PRECAUTIONS"**).

CORAL CALCIUM may interfere with the absorption and metabolism of some medications (see **"WARNINGS AND SPECIAL PRECAUTIONS"**).

Cytochrome P450 (3A4) substrates:
Vitamin D in **CORAL CALCIUM** is thought to induce CYP 3A4 and people using medication metabolised by CYP 3A4 should be advised to take **CORAL CALCIUM** cautiously. Some medication metabolised by CYP 3A4 include lovastatin, atorvastatin, clarithromycin, cyclosporine, diltiazem, estrogens, indinavir, triazolam and others.

Thiazide diuretics:
Thiazide diuretics decrease urinary calcium excretion, which could lead to hypercalcemia if **CORAL CALCIUM** is taken concurrently. **CORAL CALCIUM** should only be taken under supervision of a healthcare professional if taken with thiazide diuretics. Thiazide diuretics include: chlorothiazide, hydrochlorothiazide, indapamide, metolazone, chlorthalidone and others.

Bisphosphonates:
Calcium in **CORAL CALCIUM** can decrease the absorption of bisphosphonates. Bisphosphonates should be taken on a different time of the day. Bisphosphonates include alendronate, etidronate, ibandronate, risedronate and tiludronate.
Patients should take bisphosphonates and **CORAL CALCIUM** 2 hours apart.

Dolutegravir, elvitegravir:
Calcium in **CORAL CALCIUM** could reduce the blood levels of dolutegravir and elvitegravir through chelation. Patients should take **CORAL CALCIUM** 6 hours before or 2 hours after taking dolutegravir or elvitegravir.

Quinolone antibiotics:
Taking **CORAL CALCIUM** at the same time as oral quinolone antibiotics can reduce the quinolone absorption. Patients should take **CORAL CALCIUM** 4-6 hours before or 2 hours after taking quinolone antibiotics.

Sotalol:
Calcium in **CORAL CALCIUM** could reduce the absorption of sotalol. Patients should take **CORAL CALCIUM** 4-6 hours before or 2 hours after taking sotalol.

Tetracycline antibiotics:
Taking **CORAL CALCIUM** at the same time as oral tetracycline antibiotics can reduce the tetracycline absorption. Patients should take **CORAL CALCIUM** 4-6 hours before or 2 hours after taking tetracycline antibiotics. Some tetracycline antibiotics include doxycycline, minocycline, tetracycline and others.

HUMAN REPRODUCTION:
Pregnancy:
Safety during pregnancy has not been established.
CORAL CALCIUM should not be used during pregnancy.

Lactation:
Safety during lactation has not been established.
CORAL CALCIUM should not be used during lactation.

DOSAGE AND DIRECTIONS FOR USE:
Adults and children from 9 years: Take 2 capsules daily with a glass of water, or as prescribed by a healthcare professional. Capsules may be emptied.
Do not exceed recommended dosage.
DO NOT TAKE CONCURRENTLY WITH OTHER MEDICATION (see **"WARNINGS AND SPECIAL PRECAUTIONS"** and **"INTERACTIONS"** for the time frame between specific medicines and **CORAL CALCIUM**).

SIDE EFFECTS:
Side Effect Profile:
Gastrointestinal disorders:
Frequency unknown: Belching, flatulence, diarrhoea, and stomach upset.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
(see **"WARNINGS AND SPECIAL PRECAUTIONS"** and **"SIDE EFFECTS"**).
Symptoms of Overdosage:
Overdosage of **CORAL CALCIUM** can lead to Vitamin D toxicity and hypercalcemia. Symptoms of overdosage can include but are not limited to: azotemia, anemia, weakness, fatigue, sleepiness, headache, loss of appetite, dry mouth, metallic taste, nausea, vomiting, abdominal cramps, constipation, diarrhoea, dizziness, ringing in the ears, trouble walking, skin eruptions, muscle pain, bone pain and irritability.

Treatment of Overdosage:
In the event of an overdosage, consult a healthcare professional.
Treatment should be symptomatic and supportive.

IDENTIFICATION:
Clear, gelatin, size 0 capsule, filled with a light beige powder.

PRESENTATION:
90 capsules, packed in a round, white, securitainer and outer carton.

STORAGE INSTRUCTIONS:
Store at or below 25 °C in a cool, dry place, protected from light.
Keep tightly closed.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER/REFERENCE NUMBER:
To be allocated upon registration.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
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DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:
To be allocated upon registration.

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COMPLEMENTARY MEDICINE:
Complementary Medicine – Health Supplement.
This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

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