MODULE -1
ADMINISTRATIVE INFORMATION FOR ZEDCAL ORAL SUSPENSION

1.5.1 SUMMARY OF PRODUCT CHARECTERISTICS

1. NAME OF MEDICINAL PRODUCT
Zedcal Oral Suspension

2. QUALITATIVE QUANTITATIVE FORMULA

ITEM	DRUG NAME	SCALE mg per 5 mL	STD QTY PER ONE LITRE
1.	Purified Water BP	q.s.	Approx. 520.000 mL
2.	Elemental Calcium Use: Calcium Carbonate BP (Light)	150 mg 374.61 mg	74.922 g
3.	Elemental Magnesium Use: Magnesium Hydroxide BP (Light)	25 mg 59.98 mg	11.996 g
4.	Elemental Zinc Use: Zinc Gluconate USP	2 mg 13.94 mg	2.788 g
5.	Vitamin D3 BP (Crystalline) (Contains 200% Excess)	5mcg 200 IU	3.000 mg
6.	Sucrose BP (Crystalline)	2500 mg	500.000 g
7.	Sodium Carboxymethylcellulose BP (Cekol 2000)	10 mg	2.000 g
8.	Aluminium Magnesium Silicate BP (Veegum HV)	35 mg	7.000 g
9.	Sodium Methylparaben BP	20 mg	4.000 g
10.	Sodium Propylparaben BP	2.5 mg	0.500 g
11.	Sorbitol 70% Solution BP (Non Crystallizing)	500 mg	100.000 g
12.	Propylene Glycol BP	100 mg	20.000 g
13.	Orange Oil (5 Folds extract)	0.004 mL 3.43 mg	0.800 mL 0.686 g

14.	Peppermint Oil BP	0.0005 mL 0.455 mg	0.100 mL 0.091 g
15.	Polysorbate 80 BP (Tween – 80)	6 mg	1.200 g
16.	Butylated Hydroxyanisole BP (BHA)	6 mcg	1.200 mg
17.	Xanthan Gum USP-NF	2.5 mg	0.500 g
18.	Sodium Hydroxide BP (Pellets)	q.s.	Approx. 1.500 g
19.	Citric Acid Monohydrate BP	q.s.	Approx. 0. 100 g
20.	Nitrogen	q.s.	q. s.

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3. PHARMACEUTICAL FORM
Oral Suspension

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
Ideal for Children and Adults

Ideal for Children and infants over 6 months, who require plenty of calcium for growth, which also reduces the risk of development of enamel hypoplasia and accelerated dental caries. Calcium is also vital for men and women over 50 and during pregnancy and breastfeeding.

It is especially important to help maintain stronger bones during and after menopause.

Helps to reduce the risk of Osteoporotic fractures by increasing the bone mass and density and also the postmenopausal osteoporosis.

When diets fail to provide the daily-recommended dietary allowance for

Calcium, Zedcal is especially recommended for:

- Growing children.
- Adolescents and young adults.
- Pregnant and breast-feeding women.
- Post-menopausal women.
- Elderly men.

4.2 Posology and method of administration
As directed by Physician

4.3 Contraindications
• Diseases and/or conditions resulting in hypercalcaemia and/or hypercalciuria (e.g. myeloma, bone metastases, primary hyperparathyroidism).
• Nephrolithiasis / nephrocalcinosis
• Severe renal impairment and renal failure

4.4 Special warnings and precautions for use
None

4.5 Fertility, pregnancy and lactation

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The drug in not recommended in pregnant & breast feeding women

4.6 Effects on ability to drive and use machines
None

4.7 Overdose
Do not exceed the recommended doses. In case of overdosage consult the physician immediately.

4.8 Interaction with other medicinal products and other forms of interactions
Thiazide diuretics reduce the urinary excretion of calcium. Due to increased risk of hypercalcaemia, serum calcium should be regularly monitored during concomitant use of thiazide diuretics.

Systemic corticosteroids reduce calcium absorption. During concomitant use, it may be necessary to increase the dose of Zedcal film-coated tablets.

Simultaneous treatment with ion exchange resins such as cholestyramine or laxatives such as paraffin oil may reduce the gastrointestinal absorption of vitamin D.

Calcium carbonate may interfere with the absorption of concomitantly administered tetracycline preparations. For this reason, tetracycline preparations should be administered at least two hours before or four to six hours after oral intake of calcium.

Hypercalcaemia may increase the toxicity of cardiac glycosides during treatment with calcium and vitamin D. Patients should be monitored with regard to electrocardiogram (ECG) and serum calcium levels.

If a bisphosphonate or sodium fluoride is used concomitantly with Zedcalfilm-coated tablets, these medicinal products should be administered at least three hours before the intake of Zedcal film-coated tablet since gastrointestinal absorption may be reduced.

Rifampicin, phenytoin or barbiturates may reduce the activity of vitamin D3, since they increase the rate of its metabolism.

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The absorption of quinolone antibiotics may be impaired if administered concomitantly with calcium. Quinolone antibiotics should be taken two hours before or six hours after intake of calcium.

Calcium salts may decrease the absorption of iron, zinc or strontium. Consequently, the iron, zinc or strontium preparation should be taken at a distance of two hours from the calcium preparation.

Calcium salts may reduce the absorption of the estramustin or thyroid hormones. It is recommended that taking Zedcal film-coated tablets be spaced at least 2 hours from these medicines.

Oxalic acid (found in spinach, sorrel and rhubarb) and phytic acid (found in whole cereals) may inhibit calcium absorption through formation of insoluble compounds with calcium ions. The patient should not take calcium products within two hours of eating foods high in oxalic acid and phytic acid.

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5. Pharmacological properties

5.1 Pharmacodynamic properties

Mechanism of Action

Vitamin D increases the intestinal absorption of calcium.
Administration of calcium and vitamin D3 (colecalciferol) counteracts the increase of parathyreoid hormone (PTH), which is caused by calcium deficiency and which causes increased bone resorption.
A clinical study of institutionalised patients suffering from vitamin D deficiency indicated that a daily intake of two tablets of calcium 500 mg/Vitamin D 400 IU for six months normalised the value of the 25-hydroxylated metabolite of Vitamin D3 and reduced secondary hyperparathyroidism and alkaline phosphatases.
An 18-month double blind, placebo controlled study including 3270 institutionalised women aged 84±6 years that received supplementation of vitamin D (800 IU/day) and calcium phosphate (corresponding to 1200 mg/day of elemental calcium), showed a significant decrease of PTH secretion. After 18 month, an "intent-to treat" analysis showed 80 hip fractures in the calcium-vitamin D group and 110 hip fractures in the placebo group ($p=0.004$). A follow-up study after 36 months showed 137 women with at least one hip fracture in the calcium-vitamin D group ($n=1176$) and 178 in the placebo group ($n=1127$, $p<0.02$).

Magnesium hydroxide is an antacid with slow neutralising action and a mild laxative action

Zinc is an essential trace element involved in many enzyme systems. Severe deficiency causes skin lesion, alopecia, diarrhoea, increased susceptibility to infections and failure to thrive in children. Symptoms of less severe deficiency include distorted or absent perceptions of taste and smell and poor wound healing.

5.2 Pharmacokinetic properties

Calcium

Absorption:

The amount of calcium absorbed through the gastrointestinal tract is approximately 30% of the swallowed dose.

Distribution and metabolism:

99% of the calcium in the body is concentrated in the hard structure of bones and teeth. The remaining 1% is present in the intra- and extracellular fluids. About 50% of the total blood-calcium content is in the physiologically active ionised form with approximately 10% being complexed to citrate, phosphate or other anions, the remaining 40% being bound to proteins, principally albumin.

Elimination:

Calcium is eliminated through faeces, urine and sweat. Renal excretion depends on glomerular filtration and calcium tubular reabsorption.

Vitamin D

Absorption:

Vitamin D3 is absorbed in the small intestine.

Distribution and metabolism:

Colecalciferol and its metabolites circulate in the blood bound to a specific globulin. Colecalciferol is converted in the liver by hydroxylation to the active form 25-hydroxycolecalciferol. It is then further converted in the kidneys to 1,25 hydroxycolecalciferol. 1,25 hydroxycolecalciferol is the metabolite responsible for increasing calcium absorption. Vitamin D which is not metabolised is stored in adipose and muscle tissues.

Elimination:

Vitamin D is excreted in faeces and urine.

Magnesium salts are poorly absorbed following oral administration. Approximately one third of magnesium is absorbed from the small intestine, and excreted mainly in the urine with small amounts in breast milk and saliva.

Zinc is absorbed from the gastrointestinal tract and distributed throughout the body. The highest concentrations occur in hair, eyes, male reproductive organs and bone. Lower levels are present in liver, kidney and muscle. In blood 80% is found in erythrocytes. Plasma zinc levels range from 70 to 110µg/dL and about 50% of this is loosely bound to albumin. About 7% is amino-acid bound and the rest is tightly bound to alpha 2-macroglobulins and other proteins.

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6. Pharmaceutical particulars
6.1 List of excipients
Purified Water BP

Sucrose BP (Crystalline)

Sodium Carboxymethylcellulose BP
(Cekol 2000)

Aluminium Magnesium Silicate BP
(Veegum HV)

Sodium Methylparaben BP

Sodium Propylparaben BP

Sorbitol 70% Solution BP

(Non Crystallizing)

Propylene Glycol BP

Orange Oil (5 Folds extract)

Peppermint Oil BP

Polysorbate 80 BP (Tween – 80)

Butylated Hydroxyanisole BP (BHA)

Xanthan Gum USP-NF

Sodium Hydroxide BP (Pellets)

Citric Acid Monohydrate BP

Nitrogen

6.2 Incompatibilities
None

6.3 Shelf life
36 months

6.4 Special precautions for storage
Store below 30 ^{0}C.