For consumer information only

SMICAL®

Suspension (200 ml)

Compositions

Each 10 ml contains:

Calcium Phosphate I.P. ..... 775 mg
equivalent to elemental Calcium ..... 300 mg
equivalent to elemental Phosphorous…150 mg
Magnesium hydroxide I.P
equivalent to elemental Magnesium… 75 mg
Zinc Gluconate U.S.P.
equivalent to elemental Zinc ..... 4 mg
Vitamin D_3 I.P. ..... 800 IU
Flavoured Syrup base… ..... Q.S.
Colour… ..... Quinoline Yellow

Clinical Pharmacology

Calcium

Calcium increases plasma calcium levels and reduces calcium flux from osteocyte activity by reducing the secretion of parathyroid hormone (PTH). Calcium stimulate G-protein coupled calcium receptor on the surface of parathyroid cells. The reduction in calcium flux increases the amount of calcium deposited in bone resulting in an increase in bone mineral density. The reduction in PTH secretion also reduces the amount of vitamin D metabolized to its active form, calcidiol. Since calcidiol increases the expression of calcium dependent ATPases and transient receptor potential cation channel subfamily V member 6 (TRPV6) both of which are involved in calcium uptake from the gut, a reduction in calcidiol results in less calcium absorption. Additionally, TRPV5, the channel responsible for calcium reabsorption in the kidney, is down regulated when PTH secretion is reduced thus increasing calcium excretion via the kidneys. Another hormone, calitonin, is likely involved in the reduction of bone reabsorption during periods of high plasma calcium.

Indications

Calcium used clinically is usually prescribed as dietary supplement.

Use in special population

Pregnancy:

Calcium intake is important during pregnancy because of the potential adverse effect on maternal bone health if maternal calcium stores are depleted. Calcium supplementation during pregnancy reduces the prevalence of pre-eclampsia. Reduction in the composite outcome of maternal death or serious morbidity with calcium supplementation. Calcium supplementation in the second half of pregnancy reduces blood pressure.

Lactation:

Calcium intake is important during lactation because of the potential adverse effect on maternal bone health if maternal calcium stores are depleted.

Osteoporosis:

Continuous treatment of osteoporosis with calcium for three years is safe and significantly reduces the rate of new vertebral fractures in women with this disorder.

Calcium deficiency

Calcium is use in treatment of calcium deficiency conditions.

Osteopenia

Precautions And Warnings

Hypercalcemia/hypervitaminosis D), difficulty absorbing nutrition from food calcium not use.

Drug interactions

Calcium can decrease the absorption of other drugs such as tetracycline antibiotics, bisphosphonates, estramustine, levothyroxine and quinolone antibiotics.

Adverse Effects

Constipation or stomach upset occur. Nausea, vomiting, loss of appetite, unusual weight loss mood change, signs of kidney problems headache, increased thirst occur.

Overdose

Overdose of calcium causes trouble breathing. Nausea, vomiting, loss of appetite, weakness, tiredness drowsiness.

Phosphorus

Clinical Pharmacology

Phosphorus plays an important role in storage, release, and transfer of energy and acid-base metabolism. Phosphorus is regulated largely by PTH, which promotes phosphate release from bone and excretion by the kidney by decreasing renal tubular reabsorption.

Indications

Phosphorus used in people who cannot get enough phosphorus from their diets.

Use in special population

Contraindications

People with CKD & hyperphosphatemia avoid to take phosphorus supplements.

Drug interactions

Phosphorus is avoided when herbal products such asaspirin, digoxin, eplerenone, high blood pressure drugs (including ACE inhibitors such as lisinopril, ARBs such as valsartan), potassium supplements/salt substitutes, vitamin products (e.g., vitamin D, calcium), certain "water pills" (including potassium-sparing diuretics such as amiloride/spironolactone/triamterene) are taken.

Preventions and Warnings

Phosphorus not taking when suffering with infection with kidney stones, high phosphate/potassium/sodium levels, severe kidney disease, Adrenal gland problems.

Overdose

Overdose of phosphorus causes trouble breathing, severe diarrhea, muscle spasms.

Adverse effect

Long term use of phosphorus causes Nausea, vomiting, diarrhea, dizziness or headache.

Vitamin D3

Clinical Pharmacology

Vitamin D is hydroxylated in the liver to form 25-hydroxycholecalciferol and then undergoes further hydroxylation in the kidney to form the active metabolite 1,25 dihydroxycholecalciferol (calcitriol). In its biologically active form vitamin D3 stimulates intestinal calcium absorption, incorporation of calcium into the osteoid and release of calcium from bone tissue. In the small intestine it promotes rapid and delayed calcium uptake. The passive and active transport of phosphate is also stimulated. In the kidney, it inhibits the excretion of calcium and phosphate by promoting tubular resorption. The production of parathyroid hormone (PTH) in the parathyroid is inhibited directly by the biologically active form of vitamin D3. PTH secretion is inhibited additionally by the increased calcium uptake in the small intestine under the influence of biologically active vitamin D3.

Indications

Prevention and treatment of vitamin D deficiency states. Hypocalcemic seizures, rickets, chronic illness.

Use in special population

Pregnancy:

Maintenance doses of vitamins are generally considered safe during pregnancy. However fetal risk cannot be ruled out when administered in high doses in pregnancy.

Lactation:

Maintenance doses of vitamins are generally considered safe during lactation. However infant risk cannot be ruled out when administered in high doses during lactation.

Postmenopausal Osteoporosis:

Vitamin D_3 increase bone mineral density (BMD),increase bone density, decreased bone turnover, and decreased nonvertebral fractures. in women with a mean age of approximately 63-65 years.

Contraindications

Hypersensitivity to cholecalciferol, ergocalciferol, or vitamin D metabolites (eg calcitriol, calcifediol, alfacalcidol, calcipotriol). Hypercalcemia (exacerbation with enhanced toxicity) Hypervitaminosis D (worsening of condition, pretherapy 25-hydroxycholecalciferol levels should be considered in selected patients)

Precautions and Warnings

Vitamin D should be used with caution in patients with impairment of renal function and the effects on calcium and phosphate levels should be monitored, the risk of soft tissue calcification should be taken into account. In patients with several renal insufficiency, vitamin D in the form of Cholecalciferol is not metabolised normally and other forms of vitamin D should be used. Caution is required in patients suffering from cardiac conditions like arteriosclerosis due to the possible exacerbation related to hypercalcaemia and in patients with hyperlipidemia due to possibility of LDL elevation. Vitamin D should be prescribed with caution to patients suffering from sarcoidosis because of the risk of increased metabolism of vitamin D to its active form. These patients should be monitored with regards to the calcium content in the serum and urine. Medical Supervision is required whilst on treatment to prevent hypercalcaemia.

Drug Interactions

Calcipotriene is a drug that is similar to vitamin D. Taking vitamin D along with calcipotriene might increase the effects and side effects of calcipotriene. Taking vitamin D along with digoxin might increase the effects of digoxin (Lanoxin) and lead to an irregular heartbeat.

Taking large amount of vitamin D along with diltiazem might decrease the effectiveness of diltiazem. When given along with antacids, vitamin D increases the absorption of aluminum salts.

Adverse effects

High dose of cholecalciferol can cause weakness, fatigue, and sleepiness, and headache, loss of appetite, dry mouth, metallic taste, nausea and vomiting. Vitamin D toxicity, including nephrocalcinosis /renal failure, hypertension, and psychosis, can occur with prolonged use of cholecalciferol, relatively low doses can produce toxicity in hypersensitive infants and children.

Hypervitaminnosis D is reversible upon discontinuation of treatment unless renal damage is severe.

Overdosage

Although no long-term studies have examined higher doses of vitamin D on serum calcium levels, there are no reported cases of vitamin D intoxication to suggest that intakes of up to 4000 IU/d of vitamin D cause hypercalcemia. In healthy adults, 5 months of ingesting 10,000 IU/d of vitamin D neither caused hypercalcemia nor increased urinary calcium excretion, which is the most sensitive indicator for potential vitamin intoxication.

In case of toxicity immediate cessation of vitamin D intake is indicated, with a low-calcium diet, glucocorticoid administration, and fluid support. Vitamin D intoxication is usually reversible with these measures; gradual falls in serum calcium and mobilization of calcium from soft tissue occur. Recovery of renal function is seen unless renal damage was severe prior to treatment.

Zinc

Clinical Pharmacology

Zinc is involved in various aspects of cellular metabolism. It has been estimated that approximately 10% of human proteins may bind zinc, in addition to hundreds of proteins that transport and traffic zinc. It is required for the catalytic activity of more than 200 enzymes, and it plays a role in immune function wound healing, protein synthesis, DNA synthesis, and cell division. Zinc is absorbed in the small intestine by a carrier-mediated mechanism. Zinc particles were mainly distributed to organs including the liver, lung, and kidney. Zinc is released from food as free ions during its digestion. These freed ions may then combine with endogenously secreted ligands before their transport into the enterocytes in the duodenum and jejunum. The excretion of zinc through gastrointestinal tract accounts for approximately one-half of all zinc eliminated from the body.

Indications

Zinc use in deficiency of zinc in body. In case of Loss of sense of smell and taste, Weight loss, Pale skin, Diarrhea, White spots under finger nails.

In special population:

Pregnancy:

Lack of zinc increase in risk of low birth weight, and low zinc intake earlier in pregnancy was associated with more than a trebling of pre-term delivery.

Lactation:

Lack of zinc in Infants alopecia, diarrhea, skin lesions, taste disorders, loss of appetite, impaired immune function and neuropsychiatric changes and growth retardation.

Postmenopausal Osteoporosis:

Lack of zinc in old age women causes immune system weakens with age, and zinc deficiency may be partly to blame. Zinc is needed for night vision and may also slow the progression of macular degeneration. Macular Degeneration is a disorder of the retina that is the leading cause of severe loss of vision in older women.

Contraindications:

Zinc is contraindicated in hypersensitivity & direct IV & IM solutions.

Precautions & Warnings

Zinc is unsafe in high doses.

Drug Interaction:

Zinc interact with antibiotics such as tetracycline antibiotics, quinolone antibiotics, Cisplatin, penicillamine.

Adverse Effects:

Zinc cause nausea, vomiting, diarrhea, metallic taste, kidney and stomach damage.

Overdose

Long term use of zinc causes nausea & vomiting, Stamach pain & Diarrhea, Flu like symptoms, low good HDL cholesterol, Change in taste, Copper Deficiency, Frequent infections.

Magnesium Hydroxide

Clinical Pharmacology

Magnesium hydroxide is an antacid react with HCl in stomach to form magnesium chloride & water. it decreases the direct acid irritant effect and increases the pH in the stomach leading to inactivation of pepsin. Magnesium hydroxide enhances the integrity of the mucosal barrier of the stomach as well as improving the tone of both the gastric and esophageal sphincters. Magnesium hydroxide is absorbed very slowly through the small intestine & excreted in the urine through the kidneys.

Indication

Magnesium hydroxide used in constipation condition. It is use as laxative,

Use in special population

Pregnancy:

Magnesium hydroxide used to treat short-term constipation, which is a fairly typical pregnancy symptom. Blame pregnancy hormones like progesterone, which can slow down the passage of food and cause a build-up of waste in the GI tract. Iron supplements are another cause of constipation in pregnant women.

Lactation:

Oral absorption of magnesium by the infant is poor, so maternal magnesium hydroxide is recommend.

Postmenopausal osteoporosis:

A group of menopausal women were given magnesium hydroxide to assess the effects of magnesium on bone density

Contraindications:

Magnesium hydroxide is contra indicated in decreased kidney function, diarrhea, high amount of magnesium in the blood, low amount of sodium in the blood, dehydration, appendicitis, blockage of the stomach or intestine, seizures.

Precautions & Warnings:

In allergic conditions, In Kidney diseases, appendicitis or symptoms of appendicitis, sudden change in bowel habits that lasts for longer than 2 weeks.

Drug Interactions

Magnesium Hydroxidedecrease the absorption of other drugs such as dasatinib, delavirdine, atazanavir, gabapentin, digoxin, mycophenolate, phosphate supplements, tetracycline antibiotics, certain azole antifungals and quinolone antibiotics.

Adverse Effects

Long term use of magnesium hydroxide causes high magnesium levels slow/irregular heartbeat, slow/shallow breathing, mental/mood changes such as confusion), symptoms of dehydration, decreased urination, extreme thirst.

Overdose

Overdose of magnesium hydroxide causes severe/persistent diarrhea , muscle weakness, mental/mood changes (e.g., confusion), slow/irregular heartbeat, decreased urination, dizziness

For Therapeutic use.

Route of administration: Oral

Type of medicines: Suspension

Flavour: Delicious pineapple flavour

Dosage: As directed by the Physician

Storage: Store in a cool, dry & dark place.
Shake well before Use.

Presentation: SMICAL is available as 200 ml Suspension.

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