

EXEN-D

COMPOSITION:

Each tablet of Exen D contains:

Calcium (Calcium from Natural Origin) (B.P)500mg

Vitamin D (Cholecalciferol from Natural Origin) (B.P).....500 IU

EaD Plus contains:

Calcium (as Calcium Carbonate)(B.P)..... 500mg

Vitamin D (B.P) 800IU

Vitamin K2-M7 (B.P) 45mcg

Product conforms to Natural Originch 10ml of Exen D suspension contains:

Calcium (Calcium from Natural Origin) (B.P).....400mg

Vitamin D (Cholecalciferol from Natural Origin) (B.P).....1000 IU

Each tablet of Exen D Plus contains:

Calcium Carbonate (B.P).....500mg

Vitamin D (B.P).....2000 IU

Vitamin K2 (B.P)80mcg

Each sachet of Exen Natural Origin

DESCRIPTION:

Exen D is combination product of Calcium (Calcium from Natural Origin) & Vitamin D (Cholecalciferol from Natural Origin). This combination medication is used to prevent or treat low blood Calcium levels in people who do not get enough Calcium from their diets. It may be used to treat conditions caused by low Calcium levels such as bone loss (Osteoporosis), weak bones (Osteomalacia/Rickets), decreased activity of the parathyroid gland (Hypoparathyroidism) and a certain muscle disease (Latent tetany). It may also be used in certain patients to make sure they are getting enough Calcium (e.g. women who are pregnant, nursing or postmenopausal, people taking certain medications such as Phenytoin, Phenobarbital or Prednisone). Calcium plays a very important role in the body. It is necessary for normal functioning of nerves, cells, muscles and bones. If there is not enough Calcium in the blood, then the body will take Calcium from bones, thereby weakening bones. Vitamin D helps body to absorb Calcium and Phosphorus. Having the right amounts of Vitamin D, Calcium and Phosphorus is important for building and keeping strong bones.

Exen D Plus is a special bone-building formula. It combines Vitamin K2-M7, Calcium and Vitamin D all at clinically researched doses in one formulation. Just two tablets or one sachet a day of Exen D Plus is an effective way to protect against Osteoporosis and build stronger bones for the future.

CLINICAL PHARMACOLOGY:

Pharmacodynamics:

Cholecalciferol (Vitamin D) is a Steroid hormone that has long been known for its important role in regulating body levels of Calcium and Phosphorus, in mineralization of bone and for the assimilation of Vitamin A. Vitamin D is produced in the skin by photochemical conversion of 7-dehydrocholesterol to previtamin D by ultraviolet light. This is followed by non-enzymatic isomerization to Vitamin D. In the absence of adequate sunlight exposure, Vitamin D is an essential dietary nutrient. Vitamin D in skin is converted to 25-hydroxyvitamin D in the liver. Conversion to the active Calcium-mobilizing hormone 1,25-dihydroxyvitamin D (Calcitriol) in the kidney is stimulated by both Parathyroid hormone and Hypophosphatemia. The principal action of 1,25-dihydroxyvitamin D is to increase intestinal absorption of both Calcium and Phosphate as well as regulate serum Calcium, renal Calcium and



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Phosphate excretion, bone formation and bone resorption.

Calcium carbonate acts by directly increasing Calcium stores within the body. Calcium (Ca^{2+}) plays a vital role in the physiology and biochemistry of organisms and the cell. It plays an important role in signal transduction pathways, where it acts as a second messenger, in neurotransmitter release from neurons, contraction of all muscle cell types and fertilization. Many enzymes require Calcium ions as a cofactor, those of the blood clotting cascade being notable examples. Extracellular Calcium is also important for maintaining the potential difference across excitable cell membranes, as well as proper bone formation.

Vitamin K2-M7 helps to increase the amount of calcium deposited in bones. Exen D Plus uses the same form of Vitamin K2-M7 (Menaquinone 7), that has been shown in recent clinical studies to help build bone density. Menaquinone 7 is considered to be the most effective form of Vitamin K, better absorbed by the body. The Vitamin K2-M7 in Exen D Plus also helps to keep Calcium away from areas where it shouldn't be, such as in arteries and helps to support cardiovascular health.

Pharmacokinetics:

Absorption: Vitamin D is readily absorbed. Maximal absorption of Calcium occurs at doses of 500mg or less taken with food. Oral bioavailability depends on intestinal pH, the presence of food and dosage.

Protein binding: Vitamin D protein binding is 50 to 80 %. Calcium is rapidly distributed taken up by skeletal tissues following absorption and distribution into extracellular fluids. Bone contains 99% of the body's Calcium and the remaining 1% is approximately equally distributed between intracellular and extracellular fluids.

Metabolism: Within the liver, Cholecalciferol is hydroxylated to Calcidiol (25-hydroxycholecalciferol) by the enzyme 25 hydroxylase. Within the kidney, Calcidiol serves as a substrate for 1-alpha-hydroxylase, yielding Calcitriol (1, 25 dihydroxycholecalciferol), the biologically active form of Vitamin D. Calcium acts as a co-factor to numerous enzymes.

Excretion: Calcium is eliminated in urine, faeces and sweat. The urinary Calcium excretion depends upon glomerular filtration and tubular reabsorption of Calcium. Vitamin D is eliminated via faeces and urine.

INDICATIONS:

Exen D is useful in case of Vitamin D and Calcium deficiency in the elderly patients. In association with some treatments of Osteoporosis (a condition where bone mass decreases and bone brittleness increases), when there is deficiency or a risk of deficiency in Vitamin D and Calcium. It may also be effective in reducing Colorectal Cancer, Hypertension and helps to diminish some of the symptoms of PMS (Premenstrual syndrome).

Exen D Plus Tablet/Sachets is indicated for: Bone mineral density, Bone health, Bone strength, To reduce the risk of Osteoporosis.

DOSAGE AND ADMINISTRATION:

Exen D

Tablet: As directed by the Physician, or use 2 tablets daily (preferably with meal) for 12 years and above age group.

Suspension: As directed by the Physician, or use 2 teaspoonful suspension twice daily (preferably with meal) for 12 years and above age group. Children: 2 to 5 years: 1 teaspoonful twice daily (preferably with meal). 5-12 years: 1 - 2 teaspoonful twice daily.



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Exen D Plus

Tablet: As directed by the Physician, or use 2 tablets daily (preferably with meal) for 12 years & above age group.

Sachet: As directed by the Physician, or use 1 sachet daily.

CONTRAINDICATIONS:

Exen D/Exen D Plus is contraindicated in patients with the following conditions:

Hypercalciuria and Hypercalcaemia diseases and/or conditions resulting in Hypercalcaemia and/or Hypercalciuria (e.g. Myeloma, Bone Metastases, Primary Hyperparathyroidism)

Hypervitaminosis D

Abnormalities of the esophagus which delay esophageal emptying such as stricture or achalasia

Inability to stand or sit upright for at least 30 minutes

Hypersensitivity to any component of this product. Hypersensitivity reactions including urticaria and angioedema have been reported

Hypersensitivity to Calcium, Cholecalciferol or to any of the excipients

Kidney stones (Nephrolithiasis, Nephrocalcinosis)

Severe renal impairment and renal failure

DRUG-DRUG INTERACTIONS:

Cardiac glycosides (medicines used to treat heart problems), as they may cause more side effects

Bisphosphonates or drugs containing strontium (used in Osteoporosis)

Thiazide diuretics (medicines used to treat high blood pressure or water retention), as they may increase the amount of Calcium in blood Tetracycline and Quinolone antibiotics (medicines used to treat infections due to bacteria) Other medicines or supplements containing Vitamin D

Thyroid hormones used in cases of thyroid disease Orlistat (a medicine used to treat obesity), Ion exchange resins such as Cholestyramine or Laxatives such as Paraffin Oil, as they may reduce the amount of Vitamin D absorbed Corticosteroids, as they may decrease the absorption of Calcium

You should wait at least:

2 hours between taking Exen D/Exen D Plus and the following medicines: Medicines containing Iron or Zinc 3 hours in the event of simultaneous treatment with Tetracycline or Quinolone antibiotics (medicines used to treat infections due to bacteria) or Bisphosphonates (used in Osteoporosis)

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

SIDE EFFECTS:

Constipation or stomach upset may occur. If any of these effects persist or worsen, tell your doctor or pharmacist promptly. If your doctor has directed you to use this medication, remember that he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor immediately if any of these unlikely but serious side effects occur: Nausea/vomiting, loss of appetite, unusual weight loss, mental/mood changes, change in the amount of urine, bone/muscle pain, headache, increased thirst, increased urination, weakness, tiredness, fast/pounding heart beat. A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any symptoms of a serious allergic reaction, including: Rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.



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Pregnancy and breastfeeding

This medicine can be used during pregnancy and breastfeeding. However, you should not exceed the recommended dose.

Nursing Mothers: As Calcium and Vitamin D passes into breast milk, you have to check with your doctor first if your infant receives any other products containing Vitamin D.

Ask your doctor or pharmacist for advice before taking any medicine.

OVER DOSE:

These symptoms may occur: Loss of appetite, excessive thirst, feeling sick (nausea), vomiting, constipation, abdominal pain, muscle weakness, fatigue, mental health problems, increased urine output, bone pain, kidney stones. If such effects occur, contact your doctor immediately. If you take too many Exen D/Exen D Plus during a long time, Calcium deposits may appear in blood vessels or body tissues.

INSTRUCTIONS:

Protect from light, excessive heat and moisture.

Store in a cool & dry place below 30°C.

Keep out of reach of children.

DIRECTIONS OF RECONSTITUTION:

Shake the bottle to loosen powder, Add boiled and cool water into the bottle up to marked circle on plastic measure given inside, and shake well to make homogeneous mixture. Now again add boiled and cool water into the bottle up to marked circle on plastic measure given inside. Shake well to make a homogeneous suspension.

PRESENTATION:

Exen D tablet is available in a blister pack of 30's.

Exen D tablet is available in bottle of 60's.

Exen D suspension is available in a bottle of 120ml.

Exen D Plus tablet is available in a blister pack of 30's.

Exen D Plus sachet is available in a box of 10's.

