MAXIBON - D
Instructions
on medical use of the drug

Trade name : Maxibon -D.
INN: Cholecalciferol, calcium citrate, magnesium sulfate, zinc trihydrate .
Dosage form: Tablets for oral administration.
Composition: Each tablet contains: Active substances:
Vitamin D3 (cholecalciferol)…….20 mcg (800 IU);
Calcium (in the form of calcium citrate) …….500 mg;
Magnesium (in the form of magnesium sulfate) …… ……. ..150 mg;
Zinc (in the form of zinc citrate trihydrate)…….7,5 mg.
Description: Biconvex tablets, film-coated.
Pharmacotherapeutic group: Regulator of calcium-phosphorus metabolism.
ATX code: A12AX.
Pharmacodynamics:
A combined preparation containing vitamins, micro- and macroelements. The action is due to the properties of the ingredients.

Calcium is involved in the formation of bone tissue, reduces resorption (resorption) and increases bone density, prevents diseases of the musculoskeletal system, and helps strengthen the skeletal system and joints. Calcium citrate ensures the absorption of calcium regardless of the functional state of the gastrointestinal tract, which is applicable for the treatment of patients with reduced secretory function of the gastrointestinal tract, as well as during treatment with drugs to reduce secretion; reduces the level of bone resorption markers , which indicates a slowdown in the processes of bone tissue destruction. Calcium regulates the level of parathyroid hormone, which leads to improved regulation of calcium homeostasis; does not increase the content of oxalates and calcium in the urine, therefore does not cause the risk of kidney stones; does not block the absorption of iron, which reduces the risk of developing iron deficiency anemia.

Cholecalciferol (vitamin D3) regulates the exchange of calcium and phosphorus in the body, participates in the formation of the bone skeleton, and helps maintain bone structure. The use of calcium and vitamin D3 prevents an increase in the production of parathyroid hormone (PTH), which is a stimulator of increased bone resorption (leaching of calcium from the bones).

Magnesium is involved in the formation of muscle and bone tissue, and also takes part in protein synthesis (including type I collagen). Zinc and magnesium are necessary for the synthesis of organic bone matrix.

Zinc promotes the synthesis of sex hormones, which prevents the destruction of bone tissue. Has a beneficial effect on bone density.

Pharmacokinetics:
Calcium is absorbed from the gastrointestinal tract and eliminated from the body in urine, sweat and feces. Calcium absorption is possible due to the activity of calbindin , an enzyme in the intestinal mucosa. The biosynthesis of calbindin directly depends on calcitriol , a metabolite of vitamin D.
Vitamin D is absorbed quickly from the intestines. Penetrates into bones, liver, adrenal glands, adipose tissue, heart muscle. When vitamin D is excreted in the bile, it is reabsorbed. Partially transformed into inactive metabolites.
Magnesium: Absorption of magnesium in the gastrointestinal tract is no more than 50 % of the dose taken. 99% of magnesium in the body is found inside cells. Approximately 2/3 of intracellular magnesium is distributed in bone tissue, 1/3 is in smooth and striated muscle tissue.
Zinc is eliminated by the kidneys (10%) and intestines (90%).
Indications for use:
- for the prevention of osteoporosis and in combination for the treatment of osteoporosis of various origins: age-related, in women during menopause (natural and surgical), idiopathic, in people taking corticosteroids and immunosuppressants for a long time;
- for diseases of teeth, periodontium, etc.;
- in situations requiring additional intake of calcium, vitamin D, minerals, microelements (for example, to improve the consolidation of traumatic fractures, during pregnancy, in case of malnutrition, etc.);
- prevention and treatment of calcium, vitamin D, magnesium, zinc deficiency.

Contraindications:
- increased individual sensitivity to the components of the drug;
- vitamin D hypervitaminosis;

- hypercalcemia and/or conditions leading to hypercalcemia, such as sarcoidosis, malignancies and primary hyperthyroidism ;
- hypercalciuria ;
- renal failure;
- urolithiasis disease;
- nephrolithiasis;
- active form of tuberculosis;
- children's age up to 12 years.

With caution:

Pregnancy and lactation, renal failure.

Side effects:

The following adverse reactions were identified during post-registration use of the drug. Since information about such reactions comes voluntarily from an unknown number of people, it is not always possible to reliably estimate their frequency or establish a cause-and-effect relationship with the drug.

Gastrointestinal disorders: Abdominal pain, constipation, diarrhea, flatulence, nausea and vomiting may occur.

Immune system disorders: allergic reactions, anaphylactic reactions, anaphylactic shock.

Rare hypersensitivity reactions with associated laboratory and clinical manifestations, including asthmatic syndrome, mild to moderate reactions of the skin and/or respiratory tract and/or gastrointestinal tract and/or cardiovascular system. Symptoms may include rash, hives, swelling, itching, respiratory distress and, very rarely, severe reactions including anaphylactic shock.

Directions for use and dosage:

Take orally during meals with a sufficient amount of water (200 ml). Adults, children over 12 years of age and elderly people are recommended:

To prevent osteoporosis, deficiency of calcium, vitamin D and minerals – 1 tablet 2 times a day. The average course duration is 2 months.

In addition to specific therapy for osteoporosis, treatment of calcium, vitamin D and mineral deficiency - 1 tablet 2-3 times a day. The average course duration is 3 months.

In situations requiring therapeutic use of calcium, vitamin D and mineral supplements - 1 tablet 1-2 times daily. The average course duration is 4-6 weeks. The duration of individual treatment is determined by the attending physician.

Dosage during pregnancy:

1 tablet 1-2 times a day.

In patients with liver failure:

There is no need for dose adjustment.

The maximum daily dose should not exceed 3 tablets.

Overdose:

Vitamin D3 hypervitaminosis, hypercalcemia and hypercalciuria .

Symptoms: thirst, polyuria, loss of appetite, constipation, nausea, vomiting, dizziness, muscle weakness, headache, fainting, coma, fatigue, bone pain, mental disorders, nephrocalcinosis , abdominal pain , urolithiasis , in severe cases – cardiac arrhythmias.

With long-term use in doses above 2500 mg of calcium - kidney damage, soft tissue calcification.

If the first signs of overdose are detected, it is necessary to reduce the dose or stop using the drug and consult a doctor.

In case of hypercalciuria exceeding 7.5 mmol/day (300 mg/day), it is necessary to reduce the dose or stop taking the drug.

Treatment: rehydration , use of loop diuretics (for example, furosemide), glucocorticosteroids , calcitonin, bisphosphonates , and in severe cases, hemodialysis.

In case of accidental overdose, induce vomiting and rinse the stomach. Therapy is symptomatic.

Drug interactions:

Calcium salts can interact with many substances by changing gastric pH, affecting gastric emptying, or forming complexes with certain substances, resulting in decreased absorption of both substances. Because these interactions occur in the gastrointestinal tract, calcium supplements should be taken separately from other medications to minimize the possibility of interaction. As a rule, it is sufficient to maintain a dosage interval of at least 2 hours before or 4-6 hours after taking a calcium supplement, unless otherwise indicated.

Antibiotics and antivirals (eg, tetracyclines, fluoroquinolones): calcium reduces the absorption of tetracycline antibiotics by forming insoluble complexes. Patients should take these medications at least two hours before or 4 to 6 hours after taking calcium supplements.

Levothyroxine : Calcium reduces the absorption of levothyroxine , probably due to the formation of insoluble complexes. Patients should take levothyroxine at least 4 hours before or 4 hours after taking calcium supplements.

Phosphates, bisphosphonates and fluorides: Calcium supplements reduce the absorption of bisphosphonates . Patients should take bisphosphonates at least 30 minutes before taking calcium, but preferably at different times of the day.

Eltrombopag : There was a 59% reduction in eltrombopag plasma levels when consuming a high-fat, high-calcium breakfast (427 mg), whereas a low-calcium meal (<50 mg) had no significant effect on eltrombopag plasma levels . Calcium-rich foods and antacids containing aluminum, calcium, and magnesium showed significant reductions in systemic exposure.

Sodium fluoride: Calcium supplements impair the absorption of sodium fluoride. Patients should take sodium fluoride at least 2 hours before or 2 hours after taking calcium supplements.

Cardiac glycosides and calcium channel blockers: Hypercalcemia increases the likelihood of fatal cardiac arrhythmias with cardiac glycosides such as digoxin and reduces the effectiveness of calcium channel blockers such as verapamil for atrial fibrillation. It is recommended that serum calcium levels be monitored in people taking calcium and/or vitamin D or these drugs concomitantly.

Protease inhibitor: When products containing calcium or magnesium, including buffered products, are administered with certain protease inhibitors, decreased plasma concentrations of all of these substances may occur. Therefore, it is recommended to use a protease inhibitor 2 hours before or 1 hour after taking medications containing aluminum, calcium or magnesium. This effect has been seen with the following drugs: amprenavir , atazanavir and tipranavir .

Thiazide diuretics: Thiazide diuretics reduce calcium excretion. Due to the increased risk of hypercalcemia, serum calcium levels should be regularly monitored during concomitant use of thiazide diuretics.

Some medications may decrease the gastrointestinal absorption of vitamin D. To minimize this interaction, these medications should be taken separately from vitamin D at least 2 hours before or 4 to 6 hours after taking vitamin D. These medications include: ion exchange resins (eg, cholestyramine), laxative, orlistat , carbamazepine , phenytoin, and barbiturates increase the conversion of vitamin D to its inactive metabolite, reducing the effect of vitamin D3.

Interaction with food components: oxalic acid, phytic acid. Oxalic acid, found in spinach and rhubarb, and phytic acid, found in grains, can interfere with calcium absorption. It is not recommended to take calcium supplements within 2 hours after eating a meal containing a high concentration of oxalic and phytic acids.

Iron, zinc, magnesium: Calcium supplements may reduce the absorption of iron, zinc and magnesium from food. However, in people with normal supply of these minerals, this has no clinical significance in the long term. Patients at risk of iron, zinc, or magnesium deficiency should take calcium supplements at bedtime rather than with meals to avoid decreased absorption of micronutrients.

Dietary fiber: Some components of dietary fiber may slow calcium absorption. These include phytic acid (found in wheat bran), oxalic acid (found in spinach and rhubarb), and uronic acid (a common component of plant fibers).

Pregnancy and breastfeeding:

During pregnancy and breastfeeding, take the drug in consultation with your doctor. The daily dose for pregnant women should not exceed 1500 mg of calcium and 600 IU of vitamin D3, since hypercalcemia that develops against the background of an overdose during pregnancy can cause defects in the mental and physical development of the child. In nursing women, it should be taken into account that colecalciferol and its metabolites pass into breast milk. This should be taken into account when additionally prescribing calcium and vitamin D3 to a child.

Special instructions:

The dose should not exceed that indicated in the instructions, since increased calcium intake can inhibit the absorption of iron, zinc and other essential minerals in the intestines.

Impact on the ability to drive a car and driving mechanisms:

There is no data on the effect of the drug on the speed of psychomotor reactions when driving a car and working with precision mechanisms.

Release form and packaging:

Film-coated tablets. 10 tablets in a blister. Three blisters along with instructions for use are packed in a cardboard box.

Storage conditions:

Store in a dry place, protected from light, at a temperature not exceeding 25 0C.

Keep out of the reach of children.

Best before date:

3 years. Do not use after the expiration date indicated on the package.

Conditions for dispensing from pharmacies:

Without a doctor's prescription

Made for:

MAXX-PHARM.LTD

London, Great Britain