Produktinformationen för Calcichew-D3 Mite Apelsin 500 mg/200 IE tuggtablett, MTnr 21889, gäller vid det tillfälle då läkemedlet godkändes. Informationen kommer inte att uppdateras eftersom läkemedlet inte marknadsförs i Sverige. Av samma anledning finns inte någon svensk produktinformation.
Den engelska produktinformationen kommer dock att uppdateras för de produkter där Sverige är referensland.
Om läkemedelsnamnet i följande produktinformation inte stämmer med namnet på dokumentet, beror det på att läkemedlet i Sverige är godkänt under ett annat namn.

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Calcichew-D_3 Mite Apelsin 500 mg/200 IU chewable tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains:
Calcium carbonate equivalent to 500 mg calcium
Cholecalciferol concentrate (powder form) equivalent to 200 IU (5 microgram) cholecalciferol (vitamin D3)

Excipients:
Aspartame (E951)
Isomalt (E953)
Sorbitol (E420)
Sucrose

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Chewable tablet

Round, white and convex tablets. May have small specks.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Prevention and treatment of vitamin D and calcium deficiency.
Vitamin D and calcium supplement as an adjunct to specific osteoporosis treatment of patients who are at risk of vitamin D and calcium deficiency.

4.2 Posology and method of administration

Adjunctive therapy in osteoporosis
One chewable tablet 2-3 times per day

Calcium and vitamin D deficiency
Adults: 1 chewable tablet 1-3 times per day
Children: 1 tablet 1-2 times per day
The tablet may be chewed or sucked.

Dosage in hepatic impairment
No dose adjustment is required.

Dosage in renal impairment
Calcichew-D_3 Mite Apelsin tablets should not be used in patients with severe renal impairment.

4.3 Contraindications

- Diseases and/or conditions resulting in hypercalcaemia and/or hypercalciuria
- Nephrolithiasis
- Hypervitaminosis D
- Hypersensitivity to the active substances or to any of the excipients

4.4 Special warnings and precautions for use

During long-term treatment, serum calcium levels should be followed and renal function should be monitored through measurement of serum creatinine. Monitoring is especially important in elderly patients on concomitant treatment with cardiac glycosides or diuretics (see section 4.5) and in patients with a high tendency to calculus formation. In case of hypercalcaemia or signs of impaired renal function the dose should be reduced or the treatment discontinued.

Vitamin D should be used with caution in patients with impairment of renal function and the effect on calcium and phosphate levels should be monitored. The risk of soft tissue calcification should be taken into account. In patients with severe renal insufficiency, vitamin D in the form of cholecalciferol is not metabolised normally and other forms of vitamin D should be used (see section 4.3).

Calcichew-D_3 Mite Apelsin tablets should be prescribed with caution to patients suffering from sarcoidosis, due to the risk of increased metabolism of vitamin D into its active form. These patients should be monitored with regard to the calcium content in serum and urine.

Calcichew-D_3 Mite Apelsin tablets should be used cautiously in immobilised patients with osteoporosis due to increased risk of hypercalcaemia.

The content of vitamin D (200 IU) in Calcichew-D_3 Mite Apelsin tablets should be considered when prescribing other medicinal products containing vitamin D. Additional doses of calcium or vitamin D should be taken under close medical supervision. In such cases it is necessary to monitor serum calcium levels and urinary calcium excretion frequently. Milk-alkali syndrome (Burnett's syndrome), i.e. hypercalcaemia, alkalosis and renal impairment, can develop when large amounts of calcium are ingested with absorbable alkali.

Co-administration with tetracyclines or quinolones is usually not recommended, or must be done with precaution (see section 4.5).

Calcichew-D_3 Mite Apelsin tablets contain aspartame (E951, a source of phenylalanine). May be harmful for people with phenylketonuria.

Calcichew-D_3 Mite Apelsin tablets contain sorbitol (E420), isomalt (E953) and sucrose. Patients with rare hereditary problems of fructose intolerance, glucose- galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interactions with other medicinal products and other forms of interaction

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.

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 is used concomitantly, this preparation should be administered at least one hour before the intake of Calcichew-D_3 Mite Apelsin since gastrointestinal absorption may be reduced.

The efficacy of levothyroxine can be reduced by the concurrent use of calcium, due to decreased levothyroxine absorption. Administration of calcium and levothyroxine should be separated by at least four hours.

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.

4.6 Pregnancy and lactation

Pregnancy
During pregnancy the daily intake should not exceed 1,500 mg calcium and 600 IU vitamin D. Studies in animals have shown reproductive toxicity of high doses of vitamin D. In pregnant women, overdoses of calcium and vitamin D should be avoided as permanent hypercalcaemia has been related to adverse effects on the developing foetus. There are no indications that vitamin D at therapeutic doses is teratogenic in humans. Calcichew-D_3 Mite Apelsin can be used during pregnancy, in case of a calcium and vitamin D deficiency.

Breast-feeding
Calcichew-D_3 Mite Apelsin can be used during breast-feeding. Calcium and vitamin D3 pass into breast milk. This should be considered when giving additional vitamin D to the child.

4.7 Effects on ability to drive and use machines

There are no data about the effect of this product on driving capacity. An effect is, however, unlikely.

4.8 Undesirable effects

Adverse reactions are listed below, by system organ class and frequency. Frequencies are defined as: uncommon (>1/1,000, <1/100)**,** rare (>1/10,000, <1/1,000), or very rare (<1/10,000).

Metabolism and nutrition disorders
Uncommon: Hypercalcaemia and hypercalciuria.
Very rare: Seen usually only in overdose (see section 4.9) Milk-alkali syndrome

Gastrointestinal disorders
Rare: Constipation, flatulence, nausea, abdominal pain, and diarrhoea.
Very rare: Dyspepsia

Skin and subcutaneous tissue disorders
Very rare: Pruritus, rash and urticaria.

4.9 Overdose

Overdose can lead to hypervitaminosis and hypercalcaemia. Symptoms of hypercalcaemia may include anorexia, thirst, nausea, vomiting, constipation, abdominal pain, muscle weakness, fatigue, mental disturbances, polidipsia, polyuria, bone pain, nephrocalcinosis, renal calculi and in severe

cases, cardiac arrhythmias. Extreme hypercalcaemia may result in coma and death. Persistently high calcium levels may lead to irreversible renal damage and soft tissue calcification.
Milk-alkali syndrome may occur in patients who ingest large amounts of calcium and absorbable alkali. Symptoms are frequent urge to urinate, continuing headache, continuing loss of appetite, nausea or vomiting, unusual tiredness or weakness, hypercalcaemia, alkalosis and renal impairment.

Treatment: The treatment with calcium and vitamin D must be discontinued. Treatment with thiazide diuretics and cardiac glycosides must also be discontinued. Emptying of the stomach in patients with impaired consciousness. Rehydration, and, according to severity, isolated or combined treatment with loop diuretics, bisphosphonates, calcitonin and corticosteroids. Serum electrolytes, renal function and diuresis must be monitored. In severe cases, ECG and CVP should be followed.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Mineral supplements
ATC code: A12AX

Vitamin D increases the intestinal absorption of calcium.

Administration of calcium and vitamin D_3 counteracts the increase of parathyroid 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.

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 D is easily absorbed in the small intestine.
Distribution and metabolism: Cholecalciferol and its metabolites circulate in the blood bound to a specific globulin. Cholecalciferol is converted in the liver by hydroxylation to the active form 25-hydroxycholecalciferol. It is then further converted in the kidneys to 1,25 hydroxycholecalciferol. 1,25 hydroxycholecalciferol 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.

5.3 Preclinical safety data

At doses far higher than the human therapeutic range teratogenicity has been observed in animal studies. There is further no information of relevance to the safety assessment in addition to what is stated in other parts of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol (E420)
Povidone
Isomalt (E953)
Flavouring (orange)
Magnesium stearate
Aspartame (E951)
Mono- and diglycerides of fatty acids
All-rac-alpha-tocopherol
Sucrose
Modified maize starch
Triglycerides, medium-chain
Sodium ascorbate
Silica, colloidal anhydrous

6.2 Incompatibilities

Not applicable

6.3 Shelf life

High Density Polyethylene tablet container:
Pack sizes: 20, 30, 50, 60, 90, 100, 120 and 168 tablets: 3 years
Pack size 180 tablets: 2 years
Blister pack: 2 years

6.4 Special precautions for storage

High Density Polyethylene tablet container: Do not store above 30°C. Keep the container tightly closed in order to protect from moisture.
Blister pack: Do not store above 25°C. Store in the original package in order to protect from moisture.

6.5 Nature and content of container

The chewable tablets are packed in:
HDPE tablet containers with HDPE/LDPE screw cap, or LDPE cap or
Blister pack (PVC/PE/PVdC/Al)

Pack sizes: 20, 30, 50, 60, 90, 100, 120, 168 and 180 tablets

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements

7. MARKETING AUTHORISATION HOLDER

Nycomed AB
Box 27264
102 53 Stockholm
Sweden

8. MARKETING AUTHORISATION NUMBERS

21889

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

2005-07-01/ 2008-06-01

10. DATE OF THE REVISION OF THE TEXT

2011-11-28