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SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Finished Pharmaceutical Product

1.1 Proprietary Name

CALCIVITA FORTE

1.2 Strength

Each soft gelatin capsule contains:

Calcium Carbonate 1500mg containing Calcium 600mg and Vitamin d3 200 IU

1.3 Description

White colour, oily suspension filled in 26.1 minim, oblong, white, opaque soft gelatin shell capsule.

2. Qualitative and Quantitative Composition

2.1 Qualitative Declaration

2.2 Quantitative Declaration

Active Ingredient	Specification	Claim (mg/cap)	Content / capsule (mg)
Calcium carbonate heavy Equivalent to Calcium	BP	600.00	1500.00
Vitamin D3 1.0 MIU/g Equivalent to Vitamin D3	EP Current Edition	240.00 IU	0.24

‘For full list of excipients, see section 6.1

3. Pharmaceutical Form

Capsules, Soft Gelatin.

4. Clinical Particulars

4.1 Therapeutic Indications

- Used as a calcium and vitamin D supplement for adults

4.2 Posology and method of administration

One capsule a day or as directed by a physician.

Method of Administration: Oral

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4.3 Contraindications

Hypersensitivity to the Calcium Carbonate or cholecalciferol, or to any of the excipients of Calcivita forte.

Renal failure; hypercalciuria and hypercalcaemia and diseases and/or conditions, which lead to hypercalcaemia and/or hypercalciuria (eg, myeloma, bone metastases, primary hyperparathyroidism); kidney stones (nephrolithiasis, nephrocalcinosis); hypervitaminosis D.

4.4 4.4 Special Warnings and Precautions for Use

If you take other medications, take them at least 2 hours before or 4 to 6 hours after you take Calcium and Vitamin D combination.

4.5 Interaction with other medicinal products and other forms of interaction

Thiazide diuretics reduce calcium excretion in the urine. Because of the increased risk of hypercalcaemia, calcium monitoring is recommended in cases when thiazide diuretics are given simultaneously.

Systemic corticosteroids reduce calcium absorption. In the case of concomitant administration of corticosteroids, it might be necessary to increase the dose of Calcivita forte.

Orlistat, combined ion-exchange resin treatment eg, cholestyramine or laxatives eg, paraffin oil can reduce the gastrointestinal absorption of vitamin D₃. An interval of at least 2 hrs should be observed between ingestion of ion-exchange resins (eg, cholestyramine) or laxatives and Calcivita forte as otherwise the absorption of vitamin D₃ is reduced.

Calcium Carbonate can alter tetracycline absorption when given simultaneously. It is recommended that taking tetracycline be staggered by at least 2 hrs before or 4-6 hrs after taking calcium by mouth.

Hypercalcaemia can increase the toxicity of cardiac glycosides in the case of simultaneous administration with calcium and vitamin D. Consequently patients must be monitored regularly (ECG check and calcaemia).

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

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 2 hrs from the calcium preparation.

Calcium salts may reduce the absorption of the estramustin or thyroid hormones. It is recommended that taking Calcivita forte be spaced at least 2 hrs from these medicines.

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In the case of concomitant bisphosphonate, sodium fluoride or fluoroquinolone administration, it is recommended that taking Calcivita forte be spaced by at least 3 hrs, as their absorption during digestion may be reduced.

Oxalic acid (found in spinach and rhubarb) and phytic acid (found in wholegrain cereals) can inhibit calcium absorption by forming insoluble compound with calcium ions. Patients must not take calcium containing-products in the 2 hrs after the consumption of foods rich in oxalic acid and phytic acid.

4.6 Use in pregnancy and lactation

Should be given only if the potential benefit justifies the potential risk to the foetus.

4.7 Effects on ability to drive and use machines

None reported.

4.8 Undesirable Effects

- An irregular heartbeat;
- Weakness, drowsiness, headache;
- Dry mouth, or a metallic taste in your mouth; or
- Muscle or bone pain

4.9 Overdose

Not applicable.

5. Pharmacological properties

5.1 Pharmacodynamic Properties

Calcivita forte is a vitamin-mineral combination.

Vitamin D supplementation corrects an insufficient vitamin D intake and increases the intestinal absorption of calcium. The optimal vitamin D dose in elderly subjects is 500-1000 IU/day. Calcium supplementation balances a dietary calcium deficiency. The usual calcium requirement of the elderly is 1500 mg/day. Vitamin D and calcium supplementation correct secondary senile hyperparathyroidism.

An 18 months, double-blind, placebo-controlled study carried out in 3270 women living in institutions, aged 84±6 years and receiving a vitamin D3 supplement (800 IU/day) and calcium phosphate (corresponding to 1200 mg/day of elemental calcium) showed a significant decrease in PTH secretion. After 18 months, following an "intention to treat" (ITT) analysis 80 hip fractures were observed in the calcium vitamin D3 group and 110 hip fractures in the placebo group (p=0.004). In a follow-up study after 36 months, 137 women with at least 1 fracture of the hip were observed in the calcium vitamin D3 group (n=1176) versus 178 in the placebo group (n=1127) (p≤0.02).

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5.2 Pharmacokinetic Properties

Calcium:

Absorption: In the stomach, Calcium Carbonate releases calcium ions depending upon pH. The amount of calcium absorbed by the gastrointestinal tract is in the order of 30% of the ingested dose.

Distribution and Metabolism: 99% of calcium is stored in the hard matter of bones and teeth. The remaining one percent is found in intra- and extracellular liquids. Approximately 50% of total blood calcium is found in the physiologically active ionised form, of which approximately 10% in complexes with citrate, phosphate or other anions with 40% remaining bound to proteins, mainly albumin.

Elimination: Calcium is eliminated in the urine, faeces and in the sweat. Kidney excretion depends on glomerular filtration and calcium reabsorption by the tubules.

Vitamin D:

Absorption: Vitamin D is easily absorbed by the small intestine.

Distribution and Metabolism: Cholecalciferol and its metabolites circulate in the blood, linked to a specific alpha globulin. Cholecalciferol is metabolised in the liver by hydroxylation to its active form, 25-hydroxycholecalciferol. It is then metabolised in the kidneys to 1,25-dihydroxycholecalciferol. 1,25-dihydroxycholecalciferol is the metabolite responsible for the increase in calcium absorption. The vitamin D3 that is not metabolised is stored in adipose and muscle tissue.

Elimination: Vitamin D3 is excreted via the faeces and urine. The plasma half-life is in the order of several days.

5.3 Preclinical Safety Data

Not applicable.

6. Pharmaceutical Particulars

6.1 List of Excipients

Inactive :

Soybean Oil

Hydrogenated Vegetable Oil

White Wax

Lecithin

Capsule shell :

Gelatin

Glycerin

Purified Water

Titanium Dioxide

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6.2 Incompatibilities

None.

6.3 Shelf Life

Two years from manufacturing date.

6.4 Special Precautions for Storage

Store below 30°C in a dry place, away from direct sunlight.

6.5 Nature and Contents of Container

White HDPVC bottle with HDPVC cap containing 30 capsules with printed label.

6.6 Special precaution for disposal and other handling

No special requirements.

7. Marketing Authorization Holder and Manufacturing Site Addresses

MEGA LIFESCIENCES Public Company Limited

384 Moo 4, Soi 6, Bangpoo Industrial Estate,

Pattana 3 Road, Phraeksa, Mueang,
Samutprakarn 10280, Thailand.

8. Marketing Authorization Number: N/A

9. Date of first Registration/ Renewal of the Registration: N/A

10. Date of revision of the text: