

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Finished Pharmaceutical Product

1.1 Proprietary Name

CALCIVITA

1.2 Strength

Each softgel capsule contains:

Vitamin A Palmitate 1.0 mIU/g

Equivalent to Vitamin A..... 2500.00 IU

Vitamin D3 1.0 mIU/g

Equivalent to Vitamin D..... 400.00 IU

Calcium Phosphate Dibasic Anhydrous..... 150.00 mg

Calcium Carbonate Heavy..... 50.00 mg

1.3 Pharmaceutical Form

Capsules, Softgel

2. Qualitative and Quantitative Composition

2.1 Qualitative Declaration

Name of active ingredients
Vitamin A Palmitate
Vitamin D3
Calcium Phosphate Dibasic Anhydrous
Calcium Carbonate Heavy

*For full list of excipients, see section 6.1

2.2 Quantitative Declaration

Name of active ingredients	Grade	Quantity/ Capsule
Vitamin A Palmitate	EP Current Edition	2500 IU
Vitamin D3	EP Current Edition	400 IU
Calcium Phosphate Dibasic Anhydrous	EP Current Edition	150.00MG
Calcium Carbonate Heavy	EP Current Edition	30.00MG

3. Product description

Off white colour, oily suspension, filled in 6b minim, oval, orange, opaque soft gelatin shell capsule

4. Clinical Particulars

4.1 Therapeutic Indications

As calcium, vitamin A and vitamin D supplement in pregnant, lactating women and children.

4.2 Posology and method of administration

One capsule a day or as directed by the physician

4.3 Contraindications

Not to be used if known reaction to any of the ingredients is prevalent.

4.4 Special Warnings and Precautions for Use

None.

4.5 Interaction with other medicinal products and other forms of interaction

None reported

4.6 Fertility, pregnancy and lactation

Pregnancy and lactation women should consult the physician before taking CALCIVITA.

4.7 Effects on ability to drive and use machines

None reported.

4.8 Undesirable Effects

None.

4.9 Overdose

Overdoses of CALCIVITA in human has not been reported to date.

5. Pharmacological properties

5.1 Pharmacodynamic Properties

Not applicable.

5.2 Pharmacokinetic Properties

Not applicable.

5.3 Preclinical Safety Data

Not applicable.

6. Pharmaceutical Particulars

6.1 List of Excipients

Capsule Fill: Soyabean Oil, hydrogenated vegetable oil, Beewax white, Lecithin
LV

Capsule Shell: Gelatin, Glycerin and Purified water

Incompatibilities

None.

6.2 Shelf Life

24 months

6.3 Special Precautions for Storage

Store below 25°C in a dry place, away from direct sunlight.

6.4 Nature and Contents of Container

CALCIVITA is available as 10 soft gelatin capsules packed in an Alu-PVC/PVDC blister, 5 such blisters further packed in a cardboard carton along with a pack insert.

7. Special precaution for disposal and other handling

No special requirements.

8. 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.

9. Marketing Authorization Number :

Rwanda: N/A

10. Date of first Registration/ Renewal of the Registration:

N/A

11. Date of revision of the text: March 2024