

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Kalcipos-D forte 500 mg/ 800 IU chewable tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains calcium carbonate equivalent to 500 mg calcium, cholecalciferol (Vitamin D3) 800 IU (20 microgram).

Excipients with known effect: contains glucose 200mg and sucrose 1.8mg.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable tablet

Product imported from the United Kingdom.

White to off white, round, engraved R152 on one side, diameter 17 mm.

4 CLINICAL PARTICULARS

As per PA1051/008/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1051/008/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid spray dried glucose
Magnesium stearate
Sodium citrate
Xylitol
All-rac-alfa-tocopherol
Acacia
Sodium laurilsulfate
Sucrose
Medium chain triglycerides
Starch sodium octenyl succinate (E 1450)
Silicon dioxide
Sodium ascorbate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on outer package of the product on the market in the

country of origin.

Shelf-life after first opening container: 6 months

6.4 Special precautions for storage

Store in the original container, in order to protect from light. Keep container tightly closed in order to protect from moisture.

6.5 Nature and contents of container

30 chewable tablets in plastic containers of HDPE with screw caps made of HDPE.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/161/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th November 2015

10 DATE OF REVISION OF THE TEXT