

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Osteofos D3 1200mg/800 I.U. powder for oral suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains:

Colecalciferol (Vitamin D3) 20 micrograms (equivalent to 800 I.U.)

Calcium phosphate 3100 mg

(equivalent to 1200 mg or 30 mmol of elemental calcium per sachet)

Excipients: also contains 2mg Sunset yellow FCF (E110) per dose and not more than 8.8 mg sucrose per dose

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral suspension

Product imported from Italy.

White or slightly orange, granular powder.

4 CLINICAL PARTICULARS

As per PA0865/007/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0865/007/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol

Sunset yellow FCF (E110)

Lemon flavouring (containing: natural flavourings, maltodextrin, gum arabic)

Saccharin sodium

Anhydrous citric acid

Microcrystalline cellulose and carmellose sodium

Monopalmitate sucrose

Silica colloidal anhydrous

Mannitol

α -tocopherol

Edible fats

Gelatin

Sucrose

Maize starch

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the container and outer carton of the product on the market in the country of origin.

Shelf life after reconstitution: use immediately.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Single, paper-aluminium-polythene bonded, sealed sachets.
The sachets are packaged in cardboard boxes containing 2, 30 or 60 sachets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

The appearance of the reconstituted product is a smooth orange opaque suspension with visible white granules.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/096/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 11th July 2014

10 DATE OF REVISION OF THE TEXT

August 2017