

# 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 Sunset yellow FCF (E110) and sucrose

For a full list of excipients see section 6.1.

## 3 PHARMACEUTICAL FORM

Powder for oral suspension

*Product sourced from Italy*  
White or slightly orange, granular powder.

## 4 CLINICAL PARTICULARS

As per PA 0865/007/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA 0865/007/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Propylene glycol  
Sunset yellow FCF (E110)  
Lemon flavouring  
Saccharin sodium  
Anhydrous citric acid  
Microcrystalline cellulose  
Carmellose sodium  
Monopalmitate sucrose  
Silica colloidal anhydrous  
Mannitol

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf-life expiry date of this product shall be the date shown on the sachet and outer package 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. Store in original package.

#### **6.5 Nature and contents of container**

Single, paper-aluminium-polythene bonded, sealed sachets.

The sachets are packaged in cardboard boxes containing 30 sachets.

#### **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**

PCO Manufacturing  
Unit 10, Ashbourne Business Park  
Rath  
Ashbourne  
Co. Meath  
Ireland

### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA 0465/278/001

### **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 5th August 2011

### **10 DATE OF REVISION OF THE TEXT**

May 2016