

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Desunin 800 IU Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains colecalciferol (vitamin D₃) 800 IU (equivalent to 20 microgram vitamin D₃).

Excipients with known effect:

Each tablet contains isomalt and sucrose

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from The Netherlands

White to light yellow, biconvex, 7 mm in diameter.

4 CLINICAL PARTICULARS

As per PA2010/058/001

5 PHARMACOLOGICAL PROPERTIES

As per PA2010/058/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pregelatinized maize starch

Isomalt (E 953)

Magnesium stearate

Sucrose

Sodium ascorbate

Triglycerides, medium chain

Silica, colloidal anhydrous

Sodium starch octenyl succinate (E1450)

All-rac-alpha-tocopherol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the blister and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 30°C. Store the tablets in the original container, in order to protect from light. Keep the container tightly closed in order to protect from moisture.

6.5 Nature and contents of container

90 tablets in white opaque PVC/PVDC/aluminium blister in outer paper carton.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/116/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th April 2018

10 DATE OF REVISION OF THE TEXT

November 2021