

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Ursofalk 250 mg hard capsules

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 250mg of ursodeoxycholic acid.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Capsule, hard

*Product imported from the UK, Spain and Slovakia:*

White, opaque, hard gelatin capsule containing a white compressed powder or granules.

## 4 CLINICAL PARTICULARS

As per PA 0573/005/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA 0573/005/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Maize starch  
Colloidal anhydrous silica  
Magnesium stearate  
Gelatin  
Titanium dioxide  
Sodium lauryl sulfate

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf-life expiry date of 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 25°C. Keep the capsules in the original package in order to protect from light and moisture.

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

PVC/Aluminium blisters strips packed in a carton to contain 100 capsules.

## **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**

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

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/056/001

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

Date of first authorisation: 9th September 2011.

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

July 2016