

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Ursofalk 250 mg Hard Capsules

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 250 mg ursodeoxycholic acid

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Capsule, hard (capsule).

*Product imported from Czech Republic;*

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

## 4 CLINICAL PARTICULARS

As per PA0573/005/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0573/005/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Magnesium stearate  
Maize starch  
Silica, colloidal anhydrous  
Gelatin  
Titanium dioxide (E171)  
Sodium laurilsulfate  
Purified water

### 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 strips and outer carton of the product as marketed in the country of origin.

### 6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

### 6.5 Nature and contents of container

Over-labelled cardboard carton containing 4 blister strips (25 capsules per blister).

Pack size of 100 capsules.

OR

Re-boxed cardboard carton containing 10 blister strips (10 capsules per blister).

Pack size of 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**

PPA1463/144/001

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

Date of first authorisation: 24<sup>th</sup> September 2009

**10 DATE OF REVISION OF THE TEXT**

March 2023