

# 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 (UDCA).

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Hard capsule

*Product imported from Spain, Portugal and Romania*

White opaque hard gelatin capsules 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

*Product imported from Spain and Portugal*

Magnesium stearate

Maize starch

Colloidal anhydrous silica

Gelatin

Titanium dioxide (E171)

Sodium lauryl sulfate

*Product imported from Romania*

Magnesium stearate

Maize starch

Colloidal anhydrous silica

Capsule shell:

Gelatin

Titanium dioxide (E171)

Sodium lauryl sulfate

Purified water

### 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 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**

Blisters of 60 or 100 hard capsules.

Not all pack sizes may be marketed.

#### **6.6 Special precautions for disposal**

No special requirements.

### **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

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

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

PPA0465/183/001

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

Date of first authorisation: 20 November 2006

Date of last renewal: 20 November 2011

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

September 2022