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

February 2025