Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ursofalk 250 mg Hard Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 250mg ursodeoxycholic acid
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, hard (capsule).
Product imported from Czech Republic and Slovakia;
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

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

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

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: 24th July 2009

10 DATE OF REVISION OF THE TEXT

April 2022