Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ursofalk 500 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One Ursofalk 500 mg film-coated tablet contains 500 mg of ursodeoxycholic acid (UDCA) as the active substance.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablets

Product imported from Portugal and Poland
Appearance: white, oval, biconvex film-coated tablets with a breakline on both sides. The tablet may be divided into equal doses.

4 CLINICAL PARTICULARS

As per PA0573/005/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0573/005/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Magnesium stearate
Polysorbate 80
Povidone K25
Cellulose, microcrystalline
Silica, colloidal anhydrous
Crospovidone (type A)
Talc

Coating:
Hypromellose
Macrogol 6000
Talc

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

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Transparent, colourless PVC/PVDC film, welded with hot seal lacquer to aluminium foil.

Pack sizes:
Packs of 50 and 100 film-coated tablets

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

PPA0465/183/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th March 2021

10 DATE OF REVISION OF THE TEXT

January 2023