

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ursofalk 500 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 500 mg of ursodeoxycholic acid (UDCA).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablets

Product sourced from Portugal:

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

PVC/AL blister packs of 100 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