

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ursofalk 250 mg Hard Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 250mg of ursodeoxycholic acid (UDCA) as the active substance.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, hard.

Product imported from Portugal

Ursofalk capsules are white and opaque and contain a powder or granules of white colour.

4 CLINICAL PARTICULARS

As per PA0573/005/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0573/005/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch
Anhydrous colloidal silica
Magnesium stearate
Gelatine
Titanium dioxide (E171)
Purified water
Sodium lauryl sulfate

6.2 Incompatibilities

Not known.

6.3 Shelf life

The shelf life expiry date for 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

Do not store above 25°C.

6.5 Nature and contents of container

Blister packs packed in cardboard cartons to contain 100 Hard capsules.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon Pharmaceuticals (Ireland) Limited
Block 3
Harcourt Centre
Harcourt Road
Dublin 2
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/006/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31st March 2017

10 DATE OF REVISION OF THE TEXT

October 2021