

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 of ursodeoxycholic acid.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, hard

Product imported from the UK:

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

Magnesium stearate
Maize starch
Colloidal anhydrous silica
Capsule Shell
Gelatin
Titanium dioxide (E171)
Sodium lauryl sulphate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product is 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

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

PVC/Aluminium blister packs packed in cardboard cartons to contain 100 capsules (4 strips each containing 25 capsules).

6.6 Special precautions for disposal and other handling

Not applicable.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Primecrown 2010 Ltd
4/5 Northolt Trading Estate
Belvue Road, Northolt
Middlesex UB5 5QS
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1633/016/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st December 2011

10 DATE OF REVISION OF THE TEXT

February 2018