

## 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 Slovakia

White opaque hard gelatin capsules (size 0) 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

maize starch  
magnesium stearate  
colloidal silica

#### Capsule Shell

titanium dioxide (E171)  
gelatin  
sodium lauryl sulfate  
purified water

#### 6.2 Incompatibilities

Not applicable.

#### 6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on each 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**

PVC/Aluminium blister packs packed in cardboard cartons to contain 100 capsules (10 strips each containing 10 capsules or 4 strips each containing 25 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**

LTT Pharma Limited  
Unit 18  
Oxleasow Road  
East Moons Moat  
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Worcestershire  
B98 0RE  
United Kingdom

### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1562/167/001

### **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 4th December 2015

### **10 DATE OF REVISION OF THE TEXT**