

# 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 a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated tablets

*Product imported from Czech Republic and Norway:*

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 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**

Ursofalk 500 mg film-coated tablets are available in blisters of 100 film-coated tablets.

#### **6.6 Special precautions for disposal**

No special requirements

### **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

IMED Healthcare Ltd.,  
Unit 625 Kilshane Avenue  
Northwest Business Park  
Ballycoolin  
Dublin 15  
Ireland

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

PPA1463/144/002

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

Date of first authorisation: 20<sup>th</sup> June 2025

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

April 2026