

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Salofalk 1 g Suppositories

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each suppository contains 1 g mesalazine.  
For the full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Suppositories

*Product imported from Poland:*  
light beige coloured, torpedo-shaped suppositories

## 4 CLINICAL PARTICULARS

As per PA0573/004/004

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0573/004/004

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Hard fat

### 6.2 Incompatibilities

Not applicable

### 6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the container and outer carton of the product on the market in the country of origin.

### 6.4 Special precautions for storage

Do not store above 30°C.  
Store in the original container in order to protect from light.

### 6.5 Nature and contents of container

Package sizes: 30  
Container (strip): PVC/polyethylene film.

### 6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local 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**

PPA1463/212/001

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

Date of first authorisation: 14<sup>th</sup> August 2023

**10 DATE OF REVISION OF THE TEXT**