

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Pentasa 1 g Suppositories

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each suppository contains mesalazine 1 g.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Suppository

*Product imported from Slovakia:*

White to tan, spotted, oblong suppository.

## 4 CLINICAL PARTICULARS

As per PA1009/006/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1009/006/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Povidone  
Macrogol 6000  
Magnesium stearate  
Talc

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf-life expiry date 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

Do not store above 25°C.  
Store in the original package in order to protect from light.

### 6.5 Nature and contents of container

Each suppository is individually packed in double aluminium foil and presented in cartons of 28 suppositories.

**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**

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

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/190/003

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

Date of first authorisation: 2<sup>nd</sup> May 2025

**10 DATE OF REVISION OF THE TEXT**