

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Pentasa 1 g prolonged-release tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains mesalazine 1 g.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Prolonged-release tablet.

*Product imported from Italy:*

White-grey to pale brown, speckled, oval tablet. Embossing on both sides: PENTASA.

## 4 CLINICAL PARTICULARS

As per PA1009/006/007

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1009/006/007

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Povidone  
Ethylcellulose  
Magnesium stearate  
Talc  
Microcrystalline cellulose

### 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 as the product is sensitive to light.

### 6.5 Nature and contents of container

Aluminium foil blisters, containing 60 tablets, presented in cardboard cartons.

## **6.6 Special precautions for disposal**

No special requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

PCO Manufacturing Ltd.  
Unit 10, Ashbourne Business Park  
Rath  
Ashbourne  
Co. Meath  
Ireland

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/450/003

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

Date of authorisation: 31<sup>st</sup> March 2023

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