

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Pentasa Sachet 1g prolonged-release granules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains 1 g mesalazine.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged release granules

Product imported from Belgium:

White-grey to pale white-brown granules.

4 CLINICAL PARTICULARS

As per PA1009/006/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1009/006/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethylcellulose

Povidone

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

The granules should be used immediately after first opening of the sachet.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Aluminium foil sachets

Pack sizes: 1x50 sachets

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/450/006

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th March 2025

10 DATE OF REVISION OF THE TEXT