

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Pentasa Sachet 4 g prolonged-release granules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains 4 g mesalazine.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged release granules

Product imported from Spain:

White-grey to pale white-brown granules.

4 CLINICAL PARTICULARS

As per PA1009/006/008

5 PHARMACOLOGICAL PROPERTIES

As per PA1009/006/008

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethylcellulose

Povidone

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product shall be the date shown on the sachet and outer package of the product on the market in the country of origin.

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 sachet

Pack sizes: 1 x 30 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

PPA0465/450/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th May 2023

10 DATE OF REVISION OF THE TEXT