

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Pentasa Sachet 2 g prolonged-release granules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains 2 g mesalazine

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged release granules

Product imported from Greece, Spain, France and Norway:

White-grey to pale white-brown granules.

4 CLINICAL PARTICULARS

As per PA1009/006/006

5 PHARMACOLOGICAL PROPERTIES

As per PA1009/006/006

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 is 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

Store in the original outer packaging in order to protect from light.

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Aluminium foil sachets

Pack size: 1 x 60 sachets

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

PPA1463/190/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th March 2022

10 DATE OF REVISION OF THE TEXT

June 2026