

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 container 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

Pack of 60 tablets.

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

PPA1463/110/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th December 2022

10 DATE OF REVISION OF THE TEXT