

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Pentasa 1g Suppositories

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each suppository contains mesalazine 1g.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suppository

Product imported from Lithuania:

White to tan, spotted, oblong suppository.

4 CLINICAL PARTICULARS

As per PA1009/006/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1009/006/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Povidone
Macrogol 6000
Magnesium stearate
Talc

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 in order to protect from light.

6.5 Nature and contents of container

Each suppository is individually packed in double aluminium foil and presented in cartons of 28 suppositories.

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

PPA0465/450/005

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd August 2024

10 DATE OF REVISION OF THE TEXT