

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Pentasa 500 mg prolonged-release tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each prolonged-release tablet contains 500 mg mesalazine

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged-release tablet

Product imported from Portugal and Italy.

White-grey to pale brown, speckled, round, prolonged release tablets, scored and marked '500mg' on one side and 'PENTASA' on the reverse side.

4 CLINICAL PARTICULARS

As per PA1009/006/005

5 PHARMACOLOGICAL PROPERTIES

As per PA1009/006/005

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

Aluminium foil blisters, containing 100 tablets, presented in cardboard cartons.

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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/450/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Last updated May 2020

10 DATE OF REVISION OF THE TEXT

January 2022