

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Pentasa 500 mg Prolonged-release Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains mesalazine 500mg.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged-release tablet

Product imported from the UK, Italy and Portugal:

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 is 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 as the product is sensitive to light.

6.5 Nature and contents of container

Double aluminium foil blisters, containing 50 or 100 tablets, presented in a cardboard carton or an overlabelled cardboard carton.

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
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/235/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st August 2009

Last updated: September 2014

10 DATE OF REVISION OF THE TEXT

November 2016