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 500 mg.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged-release tablet.

Product imported from Romania, Norway and Slovakia
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 for 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 to protect from light.

6.5 Nature and contents of container

Double 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

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/110/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29th July 2016

10 DATE OF REVISION OF THE TEXT

March 2023