

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Pentasa 1 g suppositories

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each suppository contains 1 g mesalazine.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suppository
Product imported from Romania
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 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 in order to protect from light.

6.5 Nature and contents of container

Blisters of 28 suppositories together with 28 finger protectors.

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

Originalis B.V.
Joop Geesinkenweg 901
1114 AB Amsterdam-Duivendrecht
Netherlands

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA2306/010/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st February 2019

10 DATE OF REVISION OF THE TEXT