

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Pentasa 1g Suppositories

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each suppository contains 1g of mesalazine.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suppository

Product imported from Spain

White to tan, spotted, oblong suppository.

4 CLINICAL PARTICULARS

As per PA 1009/006/002.

5 PHARMACOLOGICAL PROPERTIES

As per PA 1009/006/002

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

Each suppository is individually packed in double aluminium foil and presented in cartons of 28 suppositories with rubber protectors for the administration.

6.6 Special precautions for disposal

No special requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon Pharmaceuticals (Ireland) Limited
Block 3, Harcourt Centre,
Harcourt Road,
Dublin 2,
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/048/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9th September 2022

10 DATE OF REVISION OF THE TEXT