

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Asacolon 400 mg Gastro-Resistant Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gastro-resistant tablet contains: Mesalazine 400 mg.

Excipient with known effect: lactose, *see section 4.4.*

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gastro-resistant Tablet.

Product imported from the United Kingdom

The tablets are reddish to brownish and oblong-shaped.

4 CLINICAL PARTICULARS

As per PA2018/001/001

5 PHARMACOLOGICAL PROPERTIES

As per PA2018/001/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Sodium starch glycolate (Type A)
Triethyl citrate
Talc (E553b)
Methacrylic acide - methylmethacrylate copolymer (1:2)
Povidone E1201
Magnesium stearate (vegetable origin)
Iron oxides E172
Macrogol 6000

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 moisture.

6.5 Nature and contents of container

Blister strips contained within an outer cardboard carton, containing 100 tablets.

6.6 Special precautions for disposal

No special requirements for disposal. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon (UK) Ltd
Unit 18, Oxleasow Road
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Worcestershire
B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1097/008/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th May 2017

10 DATE OF REVISION OF THE TEXT

March 2020