

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Asacolon 800mg Gastro-resistant Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gastro-resistant tablet contains: 800mg mesalazine

Excipient with known effect: lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gastro-resistant tablet.

Product imported from the UK

The tablets are reddish to brownish and oblong-shaped.

4 CLINICAL PARTICULARS

As per PA2018/001/002

5 PHARMACOLOGICAL PROPERTIES

As per PA2018/001/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Sodium starch glycolate (Type A)
Magnesium stearate (vegetable origin) (E572)
Talc (E553b)
Povidone (E1201)
Methacrylic acid-methyl methacrylate copolymer (1:2)
Triethyl citrate
Iron oxides (E172)
Macrogol 6000

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the blister strips and outer carton of the product as marketed 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

Cardboard outer containing blister strips.
Pack size: 90 gastro-resistant tablets

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. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/107/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st July 2016

10 DATE OF REVISION OF THE TEXT

February 2018