

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(s) 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 PA2018/001/002

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)
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 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 within an outer cardboard carton containing 90 tablets per pack.

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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/117/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th April 2018

10 DATE OF REVISION OF THE TEXT