Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Asacolon 800 mg Gastro-resistant Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gastro resistant tablet contains: 800 mg 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 Portugal:
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
Talc
Povidone

Film Coating
Methacrylic acid-methyl methacrylate copolymer (1:2)
Talc
Triethyl citrate
Yellow and red iron oxides
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 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

Blister strips of aluminium foil and PVC, and outer cardboard carton containing 90 tablets per pack.

6.6 Special precautions for disposal

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

PPA1463/264/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st August 2026

10 DATE OF REVISION OF THE TEXT