

## 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 Melsalazine 400mg.  
Excipient with known effect: lactose.

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 and plain on all sides.

### 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  
Magnesium stearate  
Talc  
Povidone  
Methacrylic acid-methyl methacrylate copolymer (1:2)  
Triethyl citrate  
Macrogol 6000  
Iron oxides (E172)

#### 6.2 Incompatibilities

Not applicable

#### 6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the container 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**

Cardboard outer containing blister strip of 10 tablets.  
Pack size: 100 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

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1151/107/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 19<sup>th</sup> June 2009

## **10 DATE OF REVISION OF THE TEXT**

September 2016