

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Asacolón 800 mg Gastro-resistant Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gastro-resistant tablet contains: Mesalazine 800 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 PA2018/001/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA2018/001/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Lactose monohydrate  
Sodium starch glycolate (Type A)  
Triethyl citrate  
Talc E553b  
Methacrylic acid - 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 90 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  
East Moons Moat  
Redditch  
Worcestershire  
B98 0RE  
United Kingdom

### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1097/008/002

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

Date of first authorisation: 19<sup>th</sup> May 2017

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

March 2020