

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Salazopyrin® EN Tabs 500 mg Gastro-resistant tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 500 mg of sulfasalazine.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Gastro-resistant tablet

*Product imported from Hungary and the Czech Republic:*

Orange/yellow, oval-shaped tablets with 'KPh' imprinted on one side and '102' on the other.

## 4 CLINICAL PARTICULARS

As per PA0822/196/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0822/196/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Maize starch  
Magnesium stearate  
Silica, colloidal anhydrous  
Cellulose acetate phthalate  
Macrogol  
White wax  
Carnauba wax  
Glyceryl monostearate  
Talc  
Propylene glycol

### 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 carton of the product on the market in the country of origin.

#### **6.4 Special precautions for storage**

Do not store above 25°C. Keep the container tightly closed in order to protect from moisture.

#### **6.5 Nature and contents of container**

Overlabelled polyolefin rectangular HDPE pot with orange knurled cap, designed for easy opening, and containing 100 tablets in an overlabelled carton.

#### **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**

Take the tablet(s) whole with water. Do not break or crush.

### **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

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

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

PPA1463/059/001

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

Date of first authorisation: 20<sup>th</sup> April 2012

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

September 2021