

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.

Excipients with known effect:

Salazopyrin En-Tabs 500mg contains 5 mg propylene glycol in each tablet.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gastro-resistant tablet

Product imported from Hungary:

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

Povidone
Maize starch
Magnesium stearate
Silica, colloidal anhydrous
Cellulose acetate phthalate
Macrogol
White wax
Carnauba wax
Glyceryl monostearate
Talc
Propylene glycol (E1520)

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: 20th April 2012

10 DATE OF REVISION OF THE TEXT

October 2023