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, Italy and 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
Colloidal anhydrous silica
Cellacefate
Propylene glycol (E1520)
Carnauba wax
Macrogol 20,000
Glyceryl monostearate
Talc

Product from Italy also contains:
Povidone
Beeswax

Product from Hungary also contains:
Povidone
White wax

Product from The Czech Republic also contains:
Povidone
White wax

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.

Blister pack: Store in original package.
Bottle: Keep the bottle tightly closed in order to protect from moisture.

6.5 Nature and contents of container

Blister packs and square plastic containers of 100 tablets.

Not all pack sizes may be marketed.

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

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/160/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 09 September 2005

Date of last renewal: 09 September 2010

10 DATE OF REVISION OF THE TEXT

January 2024