Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Mezavant XL 1200 mg gastro-resistant, prolonged release tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 1200 mg mesalazine.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gastro-resistant, prolonged release tablets.

Product imported from Norway
Red-brown, ellipsoidal, film-coated tablet (dimensions 20.5 × 9.5 × 7.5 mm), debossed on one side with S476.

4 CLINICAL PARTICULARS

As per PA23211/004/001

5 PHARMACOLOGICAL PROPERTIES

As per PA23211/004/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Carmellose sodium
Carnauba Wax
Stearic Acid
Silica, Colloidal Hydrated
Sodium Starch Glycolate (Type A)
Talc
Magnesium Stearate

Film-coating:
Talc
Methacrylic Acid - Methyl methacrylate copolymer (1:1)
Methacrylic Acid - Methyl methacrylate copolymer (1:2)
Triethylcitrate
Titanium Dioxide (E171)
Red Ferric Oxide (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

Store below 25°C.
Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Mezavant XL is supplied in foil blister strips which are contained in a cardboard box. The pack contains 60 tablets.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Originalis B.V.,
Joop Geesinkweg 901,
1114 AB Amsterdam-Duivendrecht,
The Netherlands

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA2306/023/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th May 2022

10 DATE OF REVISION OF THE TEXT