

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 1200mg mesalazine.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Gastro-resistant, prolonged release tablets.

Product imported from Italy and The Netherlands:

Red-brown, ellipsoidal, film-coated tablet, debossed on one side with 'S476'.

4 CLINICAL PARTICULARS

As per PA1575/004/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1575/004/001

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:

Methacrylic Acid-Methyl Methacrylate Copolymer (1:1)
Methacrylic Acid-Methyl Methacrylate Copolymer (1:2)
Triethylcitrate
Titanium Dioxide (E1 71)
Red Ferric Oxide (E 172)
Macrogol 6000

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the container and outer package of the product as marketed 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

Outer cardboard carton containing blister strips Pack size: 60

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/289/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th June 2012

10 DATE OF REVISION OF THE TEXT

May 2019