Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Mezavant XL 1200mg 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:
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

Carmellose sodium
Carnauba Wax
Stearic Acid
Silica, Colloidal Hydrated
Sodium Starch Glycolate
Talc
Magnesium Stearate
Methacrylic Acid Copolymer Type A, Type B
Triethylcitrate
Titanium Dioxide (E171)
Red Ferric Oxide (E172)
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

Over-labelled outer carton containing blister strips
Pack size: 60

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/153/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd June 2011

10 DATE OF REVISION OF THE TEXT

September 2019