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:
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 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

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

6.5 Nature and contents of container

Tablets are packed in a coated aluminium blister in an overlabelled carton.
Packs contain 60 tablets.

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

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/093/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th February 2014

10 DATE OF REVISION OF THE TEXT

September 2019