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 tablet

Product imported from Italy
Red-brown, ellipsoidal, film-coated tablet, debossed on one side with S476

4 CLINICAL PARTICULARS

As per PA0689/004/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0689/004/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carmellose sodium
Carnauba wax
Stearic acid
Colloidal hydrated silica
Sodium starch glycolate
Talc
Magnesium stearate
Methacrylic acid copolymer type A and type B
Triethyl citrate
Titanium dioxide (E171)
Red iron 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 blister and outer carton of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C

Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Tablets are packed in aluminium blisters containing 60 tablets in a cardboard box.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

LTT Pharma Limited
Unit 18
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East Moons Moat
Redditch
Worcestershire
B98 0RE
UK

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/114/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th September 2014

10 DATE OF REVISION OF THE TEXT

April 2018