

# 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.

Excipients: For a full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Gastro-resistant, prolonged release tablets

*Product imported from Italy*  
Oval shaped red-brown tablet with S476 imprinted on one side and plain on the other side.

## 4 CLINICAL PARTICULARS

As per PA 0689/004/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA 0689/004/001

## 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 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**

B & S Healthcare  
Unit 4, Bradfield Road  
Ruislip  
Middlesex, HA4 0NU  
United Kingdom

### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1328/198/001

### **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 8<sup>th</sup> February 2013

### **10 DATE OF REVISION OF THE TEXT**

April 2016