

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Relifex 500mg Film-coated Tablets

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 500mg of nabumetone.

For a full list of excipients, see section 6.1

### 3 PHARMACEUTICAL FORM

Film-coated tablet.

*Product imported from the UK:*

Dark red, film-coated tablets marked “Relifex” on one side and “500” on the other.

### 4 CLINICAL PARTICULARS

As per PA1051/001/001

### 5 PHARMACOLOGICAL PROPERTIES

As per PA1051/001/001

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

Sodium starch glycollate  
Sodium lauryl sulphate  
Hypromellose  
Magnesium stearate  
Microcrystalline cellulose  
Saccharin sodium  
Liquid caramel flavour  
Red carmine (E120)  
Iron oxide yellow (E172)  
Titanium dioxide (E171)  
Talc  
Polyethylene glycol 400  
Carnauba wax

#### 6.2 Incompatibilities

Not applicable.

#### 6.3 Shelf life

The shelf life expiry date of this product is the date shown on the blister strips and outer carton of the product as marketed in the country of origin

#### **6.4 Special precautions for storage**

Keep the tablets in the original container in order to protect from light.

#### **6.5 Nature and contents of container**

Cardboard outer containing a plastic bottle with a screw top cap.  
Pack size: 56 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**

Imbat Limited  
Unit L2 North Ring Business Park  
Santry  
Dublin 9

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

PPA1151/121/001

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

Date of first authorisation: 13<sup>th</sup> November 2009

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

July 2015