

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Montelukast 10 mg Film-coated Tablets

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One film-coated tablet contains 10.40 mg montelukast sodium, which is equivalent to 10 mg of montelukast.

Excipient(s) with known effect: lactose (as lactose monohydrate).

For the full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Film-coated tablet.

*Product imported from the UK:*

Beige, round, film coated tablet, debossed with "93" on one side and "7426" on the other side of the tablet

### 4 CLINICAL PARTICULARS

As per PA0749/048/003

### 5 PHARMACOLOGICAL PROPERTIES

As per PA0749/048/003

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

Core:

Sodium laurilsulphate  
Lactose monohydrate  
Hydroxypropyl cellulose  
Starch, pregelatinised (maize)  
Sodium starch glycolate (maize) (Type A)  
Magnesium stearate

Coating:

Opadry 20A23676 Yellow containing  
Hydroxypropyl cellulose  
Hypromellose  
Titanium dioxide (E171)  
Iron oxide yellow (E172)  
Iron oxide red (E172)

#### 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 on the market in the country of origin.

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

Do not store above 30°C. Keep blister in the outer carton in order to protect from light.

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

Aluminium – Aluminium blister packs:

Available in packs of 28 tablets.

### **6.6 Special precautions for disposal**

No special requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

WPR Healthcare Limited  
Unit 10,  
Ashbourne Business Park,  
Rath,  
Ashbourne,  
Co. Meath,  
Ireland

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0565/054/003

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

Date of First Authorisation: 28<sup>th</sup> November 2014

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

December 2015