

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Singulair 10 mg film-coated tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipient(s) with known effect: lactose monohydrate.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated tablet

*Product sourced from Portugal, Italy, Poland and Belgium*

Beige, rounded square, film-coated tablet with 'SINGULAIR' engraved on one side and 'MSD 117' on the other.

or

*Product sourced from Italy:*

Beige, rounded square, film coated tablet with '117' engraved on one side.

## 4 CLINICAL PARTICULARS

As per PA1286/046/004

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1286/046/004

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Microcrystalline cellulose

Lactose monohydrate

Croscarmellose sodium

Magnesium stearate

Hypromellose

Hydroxypropyl cellulose  
Titanium dioxide (E171)  
Red ferric oxide (E172)  
Yellow ferric oxide (E172)  
Carnauba wax

## **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.  
Store in the original package in order to protect from light and moisture.

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

Blister pack of 28 tablets in a cardboard carton.

## **6.6 Special precautions for disposal**

No special requirements

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

PCO Manufacturing  
Unit 10, Ashbourne Business Park  
Rath  
Ashbourne  
Co. Meath  
Ireland

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/111/001

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

Date of first authorisation: 19<sup>th</sup> March 2004

Date of last renewal: April 2011

**10 DATE OF REVISION OF THE TEXT**

November 2018