

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Singulair Paediatric 5 mg chewable tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One chewable tablet contains montelukast sodium, which is equivalent to 5 mg montelukast.

Excipient with known effect: This medicine contains aspartame (E 951)

*For the full list of excipients, see section 6.1.*

## 3 PHARMACEUTICAL FORM

Chewable Tablet

*Product imported from Italy and Poland:*

A pink, round, biconvex chewable tablet with 'Singulair' engraved on one side and 'MSD 275' on the other.

## 4 CLINICAL PARTICULARS

As per PA1286/046/003

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1286/046/003

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Mannitol  
Microcrystalline cellulose  
Hyprolose (E463)  
Red ferric oxide (E172)  
Croscarmellose sodium  
Cherry flavour  
Aspartame (E951)  
Magnesium stearate.

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf-life expiry date of this product is 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**

Blisters in packages of 28 tablets contained in an outer cardboard carton.

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

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

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

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/111/002

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

Date of first authorisation: 19 January 2007

Date of last renewal: 19 January 2012

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

July 2020