

# 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: Lactose monohydrate

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

## 3 PHARMACEUTICAL FORM

Film-coated tablet

*Product imported from Poland:*

Beige, rounded square, film-coated, size 7.9 mm x 7.9 mm with SINGULAIR engraved on one side, MSD 117 on the other.

## 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

Hyprolose (E 463)

Magnesium stearate

Film coating:

Hypromellose

Hyprolose (E 463)

Titanium dioxide (E 171)

Red and yellow ferric oxide (E 172)  
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 on the market in the country of origin.

## **6.4 Special precautions for storage**

Store below 30°C.

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

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

Aluminium blister strips in an over-labelled cardboard carton containing 28 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**

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

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

IMED Healthcare Ltd.  
Unit 625 Kilshane Avenue  
Northwest Business Park  
Ballycoolin  
Dublin 15  
Ireland

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/064/003

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

Date of first authorisation: 11<sup>th</sup> May 2012

**10 DATE OF REVISION OF THE TEXT**

November 2018