

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, Belgium and Czech Republic

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 PA23198/014/004

5 PHARMACOLOGICAL PROPERTIES

As per PA23198/014/004

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 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

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

PPA0465/111/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th March 2004

Last updated: June 2020

10 DATE OF REVISION OF THE TEXT

May 2022