

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

SINGULAIR 10mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains montelukast sodium equivalent to 10mg montelukast.

Also contains: lactose monohydrate

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product sourced from Poland:

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

4 CLINICAL PARTICULARS

As per PA0035/085/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0035/085/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose

Lactose monohydrate

Croscarmellose sodium

Hyprolose (E463)

Magnesium stearate

Film coating:

Hypromellose

Hyprolose (E463)

Titanium dioxide (E171)

Red iron oxide (E172)

Yellow iron 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 blister strips and outer carton of the product as marketed 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 packs of 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

Imbat Ltd
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/203/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th July 2013

10 DATE OF REVISION OF THE TEXT

February 2015