

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
Hydroxypropylcellulose (E 463)
Magnesium stearate

Film coating:

Hypromellose
Hydroxypropylcellulose (E 463)
Titanium dioxide (E 171)
Red ferric oxide (E 172)
Yellow ferric oxide (E 172)
Carnauba wax

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for 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

Packaged in polyamide/PVC/aluminium blister package in:

Blisters in packages 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

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/104/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th February 2014

10 DATE OF REVISION OF THE TEXT

September 2016