

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.

Excipients with known effect:

Each chewable tablet contains 1.5 mg aspartame (E 951) and up to 0.45 mg benzyl alcohol (E 1519).

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 PA23198/014/003

5 PHARMACOLOGICAL PROPERTIES

As per PA23198/014/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol
Microcrystalline cellulose
Hyprolose (E 463)
Red ferric oxide (E172)
Croscarmellose sodium
Cherry flavour containing benzyl alcohol (E 1519)
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

November 2025