

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Singulair Paediatric 4 mg chewable tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One chewable tablet contains montelukast sodium, which is equivalent to 4 mg montelukast.

Excipient with known effect: This medicine contains aspartame (E 951).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable Tablet.

Product imported from The UK and Poland:

Pink, oval, bi-convex-shaped, SINGULAIR engraved on one side, MSD 711 on the other.

4 CLINICAL PARTICULARS

As per PA1286/046/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1286/046/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol (E421)
Microcrystalline cellulose
Hyprolose (E463)
Red ferric oxide (E172)
Croscarmellose sodium
Cherry flavour
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

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 overlabelled 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

PPA0465/111/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th August 2012

10 DATE OF REVISION OF THE TEXT

July 2020