

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.

Excipient: Aspartame (E 951) 1.5 mg per tablet.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable tablet

Product imported from Poland:

Pink, round, biconvex, diameter 9.5 mm with SINGULAIR engraved on one side, MSD 275 on the other.

4 CLINICAL PARTICULARS

As per PA1286/046/003

5 PHARMACOLOGICAL PROPERTIES

As per PA1286/046/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol
Microcrystalline cellulose
Hyprolose (E 463)
Red ferric oxide (E 172)
Croscarmellose sodium
Cherry flavor
Aspartame (E 951)
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 blister strips and outer carton of the product on the market in the country of origin.

6.4 Special precautions for storage

Store below 30°C.

Store in the original package in order to protect from light and moisture.

6.5 Nature and contents of container

Aluminium blister strips in an over-labelled cardboard carton containing 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

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/064/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th May 2012

10 DATE OF REVISION OF THE TEXT

February 2017