Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Montelukast 5 mg Chewable Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One chewable tablet contains montelukast sodium (5.20 mg), which is equivalent to 5 mg montelukast.

Excipient(s) with known effect:
Each chewable tablet contains aspartame (E951)
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable Tablet.

Product sourced from the UK
Mottled pink, square shaped tablet, debossed with "93" on one side and "7425" on the other side of the tablet

4 CLINICAL PARTICULARS

As per PA0749/048/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0749/048/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol (E421)
Sodium laurilsulfate
Hydroxypropyl cellulose
Red iron oxide (E172)
Flavour cherry PHS-143671:
maltodextrins (maize) and starch modified E1450 (Waxy maize)
Aspartame (E951)
Sodium starch glycolate (maize) Type A
Magnesium stearate

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf life expiry date of 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 30ºC. Keep blister in the outer carton in order to protect from light.

6.5 Nature and contents of container

Aluminium – Aluminium blister packs:
Available is packs of 28 tablets.

6.6 Special precautions for disposal

No special requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

WPR Healthcare Limited
Unit 10, Ashbourne Business Park
Rath,
Ashbourne,
Co. Meath,
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0565/054/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th January 2015

10 DATE OF REVISION OF THE TEXT