

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Movicol 13.8g sachet, powder for oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet of Movicol contains the following active ingredients:

Macrogol 3350	13.125 g
Sodium chloride	350.7 mg
Sodium bicarbonate	178.5 mg
Potassium chloride	46.6 mg

The content of electrolyte ions per sachet when made up to 125 ml of solution is as follows:

Sodium	65 mmol/l
Chloride	53 mmol/l
Potassium	5.4 mmol/l
Bicarbonate	17 mmol/l

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution
Product imported from United Kingdom
Free flowing white powder.

4 CLINICAL PARTICULARS

As per PA0102/023/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0102/023/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acesulfame potassium (E950)
Lime and lemon flavour
(Lime and lemon flavour consisting of: acacia solids, maltodextrin, lime oil, lemon oil, citral, citric acid and water).

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.

Reconstituted solution: 6 hours

6.4 Special precautions for storage

Sachet: Do not store above 25°C.

Reconstituted solution: Store at 2 - 8°C (in a refrigerator and covered).

6.5 Nature and contents of container

Overlabelled cardboard carton containing 30 sachets

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 solution should be discarded within 6 hours.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Primecrown 2010 Ltd.
4/5 Northolt Trading Estate
Belvue Road
Northolt
Middlesex QB5 5QS
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1633/007/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th July 2010

10 DATE OF REVISION OF THE TEXT

January 2016