

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 substance:

Macrogol 3350	13.125 g
Sodium chloride	0.3507 g
Sodium bicarbonate	0.1785 g
Potassium chloride	0.0466 g

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 the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution.

Product imported from France
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 contains the following constituents: acacia gum (E414), maltodextrin, lime oil, lemon oil, citral and citric acid).

6.2 Incompatibilities

None are known.

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

Sachet: laminate consisting of four layers: low density polyethylene, aluminium, low density polyethylene and paper, in an overlabelled carton, containing 30 sachets.

6.6 Special precautions for disposal

Any unused solution should be discarded within 6 hours.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th May 2009

10 DATE OF REVISION OF THE TEXT

November 2017