

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 (Polyethylene Glycol) 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	65.00	mmol/l
Chloride	53.00	mmol/l
Potassium	5.40	mmol/l
Bicarbonate	17.00	mmol/l

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution.

Product imported from the UK:
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 K (E950)
Lime and Lemon Flavour*

*Lime and lemon flavour contains the following constituents: 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 shall be the date shown on the container and outer package of the product on the market in the country of origin.

Discard any solution not used within 6 hours.

6.4 Special precautions for storage

Sachet: Do not store above 25°C.

Solution: Do not store above 8°C. (store in a refrigerator and covered)

6.5 Nature and contents of container

13.8 g sachets contained in boxes of 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

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

B&S Healthcare
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 1328/027/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th August 2006

Date of last renewal: 25th August 2011

10 DATE OF REVISION OF THE TEXT

August 2015