

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

UK: Free flowing white powder for oral solution.

France: Powder for oral solution

Product imported from France and the UK

4 CLINICAL PARTICULARS

As per PA0102/023/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0102/023/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

UK: Acesulfame potassium (E950) as a sweetener

Lime and lemon flavour*

* (Lime and lemon flavour contains the following constituents: acacia solids, maltodextrin, lime oil, lemon oil, citral, citric acid and water).

France: Acesulfame potassium (E950) and lemon flavour

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of the product shall be the date shown on the container and outer package of the product on the market in the country of origin.

Reconstituted solution: Discard after 6 hours.

6.4 Special precautions for storage

Sachet: Do not store above 25°C.

Store in the outer carton to protect from moisture.

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

6.5 Nature and contents of container

Carton containing sachets.

Pack size: 30 sachets.

6.6 Special precautions for disposal and other handling

Any unused solution should be discarded within 6 hours.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2
North Ring Business Park
Santry
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/089/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th May 2009

10 DATE OF REVISION OF THE TEXT

September 2016