

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Movicol 13.8 g 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	350.70	mg
Sodium bicarbonate	178.50	mg
Potassium chloride	46.60	mg

The content of electrolyte ions per sachet when made up to 125ml 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 the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution.

Product imported from France and United Kingdom:
Free flowing, white powder.

4 CLINICAL PARTICULARS

As per PA1336/006/005

5 PHARMACOLOGICAL PROPERTIES

As per PA1336/006/005

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Product imported from France
Lemon flavour
Acesulfame potassium (E950)

Product imported from the UK:
Lemon and lime flavour (containing acacia solids, maltodextrin, lime oil, lemon oil, citral, citric acid and water).
Acesulfame potassium (E950)

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.

Store in the original package in order to protect from moisture.

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

6.5 Nature and contents of container

20 or 30 overlabelled sachets contained in an outer cardboard carton.

6.6 Special precautions for disposal

Any unused solution should be discarded within 6 hours.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/159/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22nd December 2005

Date of last renewal: 22nd December 2010

10 DATE OF REVISION OF THE TEXT

February 2020