

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Movicol Paediatric Plain 6.9g sachet, powder for oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet of Movicol Paediatric Plain contains the following active ingredients:

Macrogol 3350	6.563 g
Sodium Chloride	0.1754 g
Sodium Bicarbonate	0.0893 g
Potassium Chloride	0.0251 g

The content of electrolyte ions per sachet when made up to 62.5 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 the UK

Free flowing white powder

4 CLINICAL PARTICULARS

As per PA0102/023/004

5 PHARMACOLOGICAL PROPERTIES

As per PA0102/023/004

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None

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.

6.4 Special precautions for storage

Sachet: Do not store above 25°C.

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

6.5 Nature and contents of container

Pack sizes: box of 30 sachets in an overlabeled outer carton.

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 24 hours

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/159/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th January 2011

10 DATE OF REVISION OF THE TEXT

April 2017