

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Movicol Paediatric Plain 6.9 g sachet, powder for oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet of Movicol contains the following active ingredients:

Macrogol 3350	6.563 g
Sodium Chloride	0.1754 g
Sodium Hydrogen Carbonate	0.0893 g
Potassium Chloride	0.0251 g

On reconstitution in 62.5ml of water each sachet provides:

Sodium Chloride	65 mmol/l 53 mmol/l
Bicarbonate	17 mmol/l
Potassium	5.4 mmol/l

Excipients: None

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 carton of the product as marketed in the country of origin.

Reconstituted solution: 24 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

Cardboard carton containing sachets.

Pack size 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

Any unused solution should be discarded within 24 hours.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

PPA1151/089/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15th July 2016

10 DATE OF REVISION OF THE TEXT