

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 substance:

Macrogol 3350 13.1250 g
Sodium chloride 0.3507 g
Sodium bicarbonate 0.1785 g
Potassium chloride 0.0466 g

The content of electrolyte ions per sachet when made up to 125ml of solution is as follows:

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

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution.

Product imported from France:

Powder in a sachet.

4 CLINICAL PARTICULARS

As per PA0101/023/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0101/023/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lemon Flavour, Acesulfame Potassium

6.2 Incompatibilities

None are known.

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: maximum of 6 hours.

6.4 Special precautions for storage

Store in the original package in order to protect from moisture

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

Powder Sachet: (Paper / PE / Aluminium / PE)

Pack sizes: boxes of 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

Novalus Healthcare Limited
Stephenstown Industrial Park
Balbriggan
Co. Dublin
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1925/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st March 2017

10 DATE OF REVISION OF THE TEXT