

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

MOVIPREP, powder for oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The ingredients of Moviprep are contained in two separate sachets.

Sachet A contains the following active substances:

Macrogol 3350	100 g
Sodium sulfate anhydrous	7.500 g
Sodium chloride	2.691 g
Potassium chloride	1.015 g

Sachet B contains the following active substances:

Ascorbic acid	4.700 g
Sodium ascorbate	5.900 g

The concentration of electrolyte ions when both sachets are made up to one litre of solution is as follows:

Sodium	181.6 mmol/l (of which not more than 56.2 mmol is absorbable)
Sulfate	52.8 mmol/l
Chloride	59.8 mmol/l
Potassium	14.2 mmol/l
Ascorbate	29.8 mmol/l

Excipient(s) with known effect:

This product contains 0.233 g of aspartame per sachet A.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution.

Product imported from France

Free flowing white to yellow powder in Sachet A.

Free flowing white to light brown powder in Sachet B.

4 CLINICAL PARTICULARS

As per PA1336/001/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1336/001/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aspartame (E951)

Acesulfame potassium (E950)

Lemon flavouring containing maltodextrin, citral, lemon oil, essential oil of lime, xanthan gum & vitamin E

6.2 Incompatibilities

Not applicable

6.3 Shelf life

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

Reconstituted solution 24 hours

6.4 Special precautions for storage

Sachets: Store below 25°C. Store in original package.

Reconstituted Solution: Store below 25°C. The solution may be stored for up to 24 hours at room temperature or in the fridge (2°C - 8°C). Keep the solution covered.

6.5 Nature and contents of container

A sachet containing 112 g of powder ('sachet A') and a sachet containing 11 g of powder ('sachet B'). Both sachets are contained in a transparent bag. One pack of Moviprep contains a single treatment of two bags.

Pack size of 1 single treatment.

6.6 Special precautions for disposal and other handling

Reconstitution of Moviprep in water may take up to 5 minutes and is best performed by adding the powder to the mixing vessel first followed by the water. The patient should wait until all the powder has dissolved before drinking the solution.

After reconstitution in water, Moviprep consumption may begin immediately or if preferred it may be cooled before use.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

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9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 15th April 2016

10 DATE OF REVISION OF THE TEXT

December 2017