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 0.233g 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 Romania

Free flowing white to yellow powder in Sachet A.
Free flowing white to light brown powder in Sachet B.

4 CLINICAL PARTICULARS

As per PA 1336/001/001.

5 PHARMACOLOGICAL PROPERTIES

As per PA 1336/001/001.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aspartame (E951)
Potassium acesulfame (E950)

Lemon flavour containing maltodextrin, citral, lemon oil, lime oil, 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 sachets 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.
Reconstituted solution: Store below 25°C. The solution may be refrigerated. Keep the solution covered.

6.5 Nature and contents of container

A paper / low density polythene / aluminium / low density polythylene sachet containing 112 g of powder ('sachet A') and a paper / low density polythylene / aluminium / low density polythylene 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

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

Lexon Pharmaceuticals (Ireland) Limited
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/034/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th October 2020

10 DATE OF REVISION OF THE TEXT

October 2021