

MOVIPREP® מוביפרפ®**Powder for solution**

המארז מכיל שתי שקיות שקופות שכל אחת מהן מכילה זוג שקיקים: שקיק 1 ושקיק 2.

חומרים פעילים:שקיק 1 מכיל:

Macrogol 3350	100g
Sodium sulfate anhydrous	7.5g
Sodium Chloride	2.691g
Potassium Chloride	1.015g

שקיק 2 מכיל:

Ascorbic Acid	4.7g
Sodium Ascorbate	5.9g

ההתוויה הרשומה לתכשיר בישראל:

For bowel cleansing prior to any clinical procedures requiring a clean bowel e.g. bowel endoscopy or radiology.

מהות העדכונים:

עדכון עלון לרופא כולל החמרה, עדכוני נוסח בהתאם לעלון האסמכתא, תנאי הרישום ובהתאמה להנחיות משרד הבריאות.

עלון לרופא:**SUMMARY OF PRODUCT CHARACTERISTICS****Prescribing Information****1 NAME OF THE MEDICINAL PRODUCT**

Moviprep®, powder for oral solution

(...)

4.2 Posology and method of administration**Posology**

Adults and Older people: A course of treatment consists of two litres of Moviprep. It is strongly recommended that one liter-litre of clear liquid, which may include, water, clear soup, fruit juice without pulp, soft drinks, tea and/or coffee without milk, is also taken during the course of treatment.

A litre of Moviprep consists of one 'sachet 1' and one 'sachet 2' dissolved together in water to make one litre of solution. The reconstituted solution should be drunk over a period of one to two hours. This process should be repeated with a second litre of Moviprep to complete this course.

This course of treatment can be taken either as divided or as single doses ~~divided-doses, or as a single dose~~ and timing is dependent on whether the clinical procedure is conducted with or without general anaesthesia as specified below:

(...)

4.5 Interaction with other medicinal products and other forms of interaction

Medicinal products taken orally (e.g. oral contraceptive pill) one hour before, during and one hour after Moviprep administration may be flushed from the gastrointestinal tract unabsorbed. **The therapeutic effect of drugs with a narrow therapeutic index or short half-life may be particularly affected.**

Moviprep may result in a potential interactive effect if used with starch-based food thickeners. The Macrogol ingredient counteracts the thickening effect of starch, effectively liquefying preparations that need to remain thick for people with swallowing problems.

(...)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: <https://sideeffects.health.gov.il>.

In addition, you can report to Padagis via the following address: www.pPadagis.co.il

(...)

6 PHARMACEUTICAL PARTICULARS

▲ 6.1 List of excipients

Lemon flavour [V3938-1 N1](#)

Aspartame

Acesulfame Potassium

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

-The sachet should be used immediately after opening.

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.~~

Reconstituted Solution: After dissolving the two sachets in 1 litre of water to make the solution for drinking, it is possible to store for 24 hours at a temperature below 25°C or in the refrigerator (2-8°C). Keep the solution covered.

(...)

עלון לרופא המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות:
<https://israeldrugs.health.gov.il/#!/byDrug>

בברכה,
פאדאגיס ישראל סוכנויות בע"מ