SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

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 a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for oral solution.

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

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Moviprep is indicated in adults for bowel cleansing prior to any clinical procedures requiring a clean bowel e.g. bowel endoscopy or radiology.

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 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 A' and one 'sachet B' 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 as specified below:

1. Divided doses: one litre of Moviprep in the evening before and one litre of Moviprep in the early morning of the day of the procedure,

2. Single dose: two litres in the evening preceding the clinical procedure or two litres in the morning of the clinical procedure.

For the divided dose and single dose taken in the evening before the procedure there should be at least one hour between the end of intake of fluid (Moviprep or clear liquid) and the start of the colonoscopy.

For the single dose in the morning of the procedure, there should be at least two hours between the end of intake of Moviprep and at least one hour between the end of intake of any clear liquid and the start of the colonoscopy.

Patients should be advised to allow for appropriate time to travel to the colonoscopy unit.

No solid food should be taken from the start of the course of treatment until after the clinical procedure.

Paediatric population
Not recommended for the use in children below 18 year of age, as Moviprep has not been studied in the paediatric population.

Method of administration

The route of administration is for oral use. A litre of Moviprep consists of one sachet A and one sachet B dissolved together in water to make a one litre solution.

Precautions to be taken before handling or administering the medicinal product.
For instructions on reconstitution of the medicinal product before administration, see section 6.6.

4.3 Contraindications

Do not use in patients with known or suspected:
- hypersensitivity to the active substances or to any of the excipients listed in section 6.1
- gastrointestinal obstruction or perforation
- disorders of gastric emptying (e.g. gastroparesis)

- ileus
- phenylketonuria (due to presence of aspartame)
- glucose-6-phosphate dehydrogenase deficiency (due to presence of ascorbate)
- toxic megacolon which complicates very severe inflammatory conditions of the intestinal tract including Crohn's disease and ulcerative colitis.

Do not use in unconscious patients

4.4 Special warnings and precautions for use

Diarrhoea is an expected effect resulting from the use of Moviprep.

Moviprep should be administered with caution to fragile patients in poor health or patients with serious clinical impairment such as:

- impaired gag reflex, or with a tendency to aspiration or regurgitation
- impaired consciousness
- severe renal insufficiency (creatinine clearance <30 mL/min)
- cardiac impairment (NYHA grade III or IV)
- those at risk of arrhythmia, for example those on treatment for cardiovascular disease or who have thyroid disease
- dehydration
- severe acute inflammatory disease

The presence of dehydration should be corrected before the use of Moviprep.

The fluid content of Moviprep when re-constituted with water does not replace regular fluid intake and adequate fluid intake must be maintained.

Semi-conscious patients or patients prone to aspiration or regurgitation should be closely observed during administration, especially if this is via a nasogastric route.

If patients develop any symptoms indicating arrhythmia or shifts of fluid/electrolytes (e.g. oedema, shortness of breath, increasing fatigue, cardiac failure), plasma electrolytes should be measured, ECG monitored and any abnormality treated appropriately.

In debilitated fragile patients, patients with poor health, those with clinically significant renal impairment, arrhythmia and those at risk of electrolyte imbalance, the physician should consider performing a baseline and post-treatment electrolyte, renal function test and ECG as appropriate.

There have been rare reports of serious arrhythmias including atrial fibrillation associated with the use of ionic osmotic laxatives for bowel preparation. These occur predominantly in patients with underlying cardiac risk factors and electrolyte disturbance.

If patients experience symptoms such as severe bloating, abdominal distention, abdominal pain or any other reaction which makes it difficult to continue the preparation, they may slow down or temporarily stop consuming Moviprep and should consult their doctor.

This medicinal product contains 56.2 mmol of absorbable sodium per litre. To be taken into consideration by patients on a controlled sodium diet.

This medicinal product contains 14.2 mmol of potassium per litre. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

The medicinal product contains aspartame, which is a source of phenylalanine. This may be harmful for people with phenylketonuria.

4.5 Interaction with other medicinal products and other forms of interaction

Oral medication should not be taken within one hour of administration of Moviprep as it may be flushed from the gastro-intestinal tract and not absorbed. The therapeutic effect of drugs with a narrow therapeutic index or short half-life may be particularly affected.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no data on the use of Moviprep during pregnancy.
The preparation should only be used during pregnancy if considered essential by the physician.

Breast-feeding
There are no data on the use of Moviprep during lactation.
The preparation should only be used during lactation if considered essential by the physician.

Fertility
There are no data on the effects of Moviprep on fertility.

4.7 Effects on ability to drive and use machines

There is no known effect on the ability to drive and use machines.

4.8 Undesirable effects

Diarrhoea is an expected outcome of bowel preparation. Due to the nature of the intervention, undesirable effects occur in the majority of patients during the process of bowel preparation. Whilst these vary between preparations, nausea, vomiting, bloating, abdominal pain, anal irritation and sleep disturbance commonly occur in patients undergoing bowel preparation. Dehydration may occur as a result of diarrhoea and/or vomiting.

As with other macrogol containing products, allergic reactions including rash, urticaria, pruritus, dyspnoea, angioedema and anaphylaxis are a possibility.

Data from clinical studies are available in a population of 825 patients treated with Moviprep in which undesirable effect data were actively elicited. Additionally, adverse events reported in post marketing are included.

The frequency of adverse reactions to Moviprep is defined using the following convention:

Very common ≥ 1/10 (≥10%)
Common ≥ 1/100, < 1/10 (≥ 1%, < 10%)
Uncommon ≥1/1000, < 1/100 (≥ 0.1%,<1%)
Rare ≥ 1/10,000, < 1/1,000 (≥ 0.01%, < 0.1%)
Very rare < 1/10,000 (< 0.01%)
Not known (cannot be estimated from the available data)
Data from clinical studies are available in a population of 825 patients treated with Moviprep in which undesirable effect data were actively elicited. Additionally, adverse events reported in post marketing are included.

System Organ Class	Frequency	Adverse Drug Reaction
Immune system disorders	Not known	Allergic reaction including anaphylactic reaction, dyspnoea and skin reactions (see below).

Metabolism and Nutrition Disorders	Not known	Electrolyte disturbances including blood bicarbonate decreased, hyper and hypocalcaemia, hypophosphataemia, hypokalaemia and hyponatremia and changes in the blood chloride levels. Dehydration
Psychiatric Disorders	Common	Sleep disorder.
Nervous System Disorder	Common	Dizziness, headache.
	Not Known	Convulsions associated with severe hyponatraemia.
Cardiac Disorders	Not known	Transient increase in blood pressure. Arrhythmia, palpitations
Gastrointestinal Disorders	Very common	Abdominal pain, nausea, abdominal distension, anal discomfort.
	Common	Vomiting, dyspepsia.
	Uncommon	Dysphagia.
	Not known	Flatulence, retching.
Hepatobiliary disorders	Uncommon	Abnormal liver function tests
Skin and Subcutaneous Tissue Disorders	Not known	Allergic skin reactions including angioedema, urticaria, pruritus, rash, erythema.
General Disorders and Administration Site Conditions	Very common	Malaise, pyrexia
	Common	Rigors, thirst, hunger.
	Uncommon	Discomfort

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. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

To report any side effect(s):
Kingdom of Saudi Arabia

- National Pharmacovigilance Center (NPC)
- Fax: +966-11-205-7662
- Call NPC at +966-11-2038222 Exts: 2317- 2356- 2353- 2354- 2334- 2340.
- Toll- free number: 8002490000
- E-mail: npc.drug@sfda.gov.sa
- Website: www.sfda.gov.sa/npc

Other GCC States:
- Contact the relevant competent authority.

4.9 Overdose

In case of gross accidental overdosage, where diarrhoea is severe, conservative measures are usually sufficient; generous amounts of fluid, especially fruit juices, should be given. In the rare event of overdose provoking severe metabolic derangement, intravenous rehydration may be used.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Osmotically acting laxative. ATC code: A06A D

The oral administration of macrogol-based electrolyte solutions causes moderate diarrhoea and results in rapid emptying of the colon.

Macrogol 3350, sodium sulfate and high doses of ascorbic acid exert an osmotic action in the gut, which induce a laxative effect.

Macrogol 3350 increases the stool volume, which triggers colon motility via neuromuscular pathways. The physiological consequence is a propulsive colonic transportation of the softened stools. The electrolytes present in the formulation and the supplementary clear liquid intake are included to prevent clinically significant variations of sodium, potassium or water, and thus reduce dehydration risk.

5.2 Pharmacokinetic properties

Macrogol 3350 is unchanged along the gut. It is virtually unabsorbed from the gastro- intestinal tract. Any macrogol 3350 that is absorbed is excreted via the urine.

Ascorbic acid is absorbed mainly at the small intestine level by a mechanism of active transport, which is sodium dependant and saturable. There is an inverse relationship between the ingested dose and the percentage of the absorbed dose. For oral doses between 30 and 180 mg an amount of about 70-85% of the dose is absorbed. Following oral intake of up to 12 g ascorbic acid, it is known that only 2 g is absorbed.

After high oral doses of ascorbic acid and when plasma concentrations exceed 14 mg/litre, the absorbed ascorbic acid is mainly eliminated unchanged in the urine.

5.3 Preclinical safety data

Preclinical studies provide evidence that macrogol 3350, ascorbic acid and sodium sulfate have no significant systemic toxicity potential.

No studies have been carried out on the genotoxicity, carcinogenicity or toxic effect on reproduction with this product.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aspartame (E951)
Acesulfame Potassium (E950)
Lemon flavour containing maltodextrin, citral, lemon oil, lime oil, xanthan gum, vitamin E.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Sachets	3 years
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 polyethylene / aluminium / low density polyethylene sachet containing 112 g of powder (‘sachet A’) and a paper / low density polyethylene / aluminium / low density polyethylene 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 sizes of 1, 10, 40, 80, 160 and 320 packs of a single treatment. Hospital packs of 40 single treatments. Not all pack sizes may be marketed.

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. MARKETING AUTHORISATION HOLDER IN KSA

Acino Pharma AG,
Birsweg 2, 4253 Liesberg, Switzerland.

8. MARKETING AUTHORISATION NUMBER(S) IN KSA

3-5083-17

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION IN KSA

02/06/2012

10. DATE OF REVISION OF THE TEXT

03/03/2016