Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Movilief 13.7g Powder For Oral Solution, Sachet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains the following active ingredients:

Macrogol 3350	13.125 g
Sodium chloride	350.7 mg
Sodium hydrogen carbonate	178.5 mg
Potassium chloride	46.6 mg

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

Sodium	65 mmol/l
Chloride	53 mmol/l
Hydrogen carbonate	17 mmol/l
Potassium	5.4 mmol/l

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution.
A white powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

- For the treatment of chronic constipation.
- Resolving faecal impaction, defined as refractory constipation with faecal loading of the rectum and/or colon.

4.2 Posology and method of administration

Posology

Chronic constipation
A course of treatment for constipation does not normally exceed 2 weeks, although this can be repeated if required.

As for all laxatives, prolonged use is not usually recommended. Extended use may be necessary in the care of patients with serious chronic or resistant constipation secondary to multiple sclerosis (MS) or Parkinson's disease, or induced by regular constipating medication, in particular opioids or antimuscarinics.

Adults, adolescents and the elderly: 1-3 sachets daily in divided doses, according to individual response.

For extended use, the dose can be adjusted down to 1 or 2 sachets daily.

Children below 12 years old: Not recommended. Alternative products are available for children.

Faecal impaction
A course of treatment for faecal impaction does not normally exceed 3 days.

Adults, adolescents and the elderly: 8 sachets daily, all of which should be consumed within a 6 hour period.

Children below 12 years old: Not recommended. Alternative products are available for children.

Patients with impaired cardiovascular function: For the treatment of faecal impaction the dose should be divided so that no more than 2 sachets are taken in any one hour.

Patients with renal insufficiency: No dosage change is necessary for the treatment of either constipation or faecal impaction.

Method of administration

Each sachet should be dissolved in 125 ml water. For use in faecal impaction 8 sachets may be dissolved in 1 litre of water.

4.3 Contraindications

Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, ileus, severe inflammatory conditions of the intestinal tract, such as Crohn's disease and ulcerative colitis and toxic megacolon.

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Diagnosis of impaction/faecal loading of the rectum should be confirmed by physical or radiological examination of the abdomen and rectum.

Mild adverse drug reactions are possible as indicated in section 4.8. If patients develop any symptoms indicating shifts of fluids/electrolytes (e.g. oedema, shortness of breath, increasing fatigue, dehydration, cardiac failure) treatment should be stopped immediately and electrolytes measured and any abnormality should be treated appropriately.

The absorption of other medicinal products could transiently be reduced due to an increase in gastro-intestinal transit rate induced by this medicinal product (see section 4.5).

Movilief contains 0.68mmol (26mg) of potassium per sachet. This should be taken into consideration if the patient takes more than one sachet daily and has reduced kidney function, or is on a controlled potassium diet.

Movilief contains 8.13mmol (187mg) of sodium per sachet. This should be taken into consideration if the patient is on a controlled sodium diet.

4.5 Interaction with other medicinal products and other forms of interaction

Macrogol raises the solubility of medicinal products that are soluble in alcohol and relatively insoluble in water.

There is a possibility that the absorption of other medicinal products could be transiently reduced during use with this medicinal product (see section 4.4). There have been isolated reports of decreased efficacy with some concomitantly administered medicinal products, e.g. anti-epileptics.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are limited amount of data from the use of macrogol 3350 in pregnant women. Studies in animals have shown indirect reproductive toxicity (see section 5.3). Clinically, no effects during pregnancy are anticipated, since systemic exposure to macrogol 3350 is negligible.

Macrogol with electrolytes can be used during pregnancy.

Breastfeeding
No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breastfeeding woman to macrogol 3350 is negligible.

Macrogol with electrolytes can be used during breastfeeding.

Fertility
There are no data on the effects of macrogol 3350 on fertility in humans. There were no effects on fertility in studies in male and female rats (see section 5.3).

4.7 Effects on ability to drive and use machines

Movilief has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Reactions related to the gastrointestinal tract occur most commonly.

These reactions may occur as a consequence of expansion of the contents of the gastrointestinal tract, and an increase in motility due to the pharmacologic effects of the product. Mild diarrhoea usually responds to dose reduction.

The frequency of the adverse reactions listed below is defined using the following convention: Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); and very rare (<1/10,000); not known (cannot be estimated from the available data).

Immune system disorders
Very rare: Allergic reactions, including anaphylaxis, angio-oedema, dyspnoea, allergic rash, erythema, urticaria and pruritus

Metabolism and nutrition disorders
Not known: Electrolyte disturbances, particularly hyperkalaemia and hypokalaemia

Nervous system disorders
Not known: Headache

Gastrointestinal disorders
Common: Abdominal pain, diarrhoea, vomiting, nausea, dyspepsia, abdominal distension, borborygmi, flatulence, anal discomfort

General disorders and administration site conditions
Not known: Peripheral oedema

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: http://www.hpra.ie/; E-mail: medsafety@hpra.ie.

4.9 Overdose

Severe pain or distension can be treated by nasogastric aspiration. Extensive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Osmotically acting laxatives.
ATC code: A06A D65

Macrogol 3350 acts by virtue of its osmotic action in the gut, which induces a laxative effect. Macrogol 3350 increases the stool volume, which triggers colon motility via neuromuscular pathways. The physiological consequence is an improved propulsive colonic transportation of the softened stools and a facilitation of the defaecation. Electrolytes combined with macrogol 3350 are exchanged across the intestinal barrier (mucosa) with serum electrolytes and excreted in faecal water without net gain or loss of sodium, potassium and water.

For the indication of faecal impaction controlled comparative studies have not been performed with other treatments (e.g. enemas). In a non-comparative study in 27 adult patients, macrogol with electrolytes cleared the faecal impaction in 12/27 (44%) after 1 day's treatment; 23/27 (85%) after 2 days' treatment and 24/27 (89%) at the end of 3 days.

Clinical studies in the use of macrogol with electrolytes in chronic constipation have shown that the dose needed to produce normal formed stools tends to reduce over time. Many patients respond to between 1 and 2 sachets a day, but this dose should be adjusted depending on individual response.

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.

5.3 Preclinical safety data

Preclinical studies provide evidence that macrogol 3350 has no significant systemic toxicity potential, based on conventional studies of pharmacology, repeated dose toxicity and genotoxicity.

There were no direct embryotoxic or teratogenic effects in rats even at maternally toxic levels that are a multiple of 66 x the maximum recommended dose in humans for chronic constipation and 25 x for faecal impaction. Indirect embryofoetal effects, including reduction in fetal and placental weights, reduced fetal viability, increased limb and paw hyperflexion and abortions, were noted in the rabbit at a maternally toxic dose that was 3.3 x the maximum recommended dose in humans for treatment of chronic constipation and 1.3 x for faecal impaction. Rabbits are a sensitive animal test species to the effects of GI-acting substances and the studies were conducted under exaggerated conditions with high dose volumes administered, which are not clinically relevant. The findings may have been a consequence of an indirect effect of macrogol 3350 related to poor maternal condition as the result of an exaggerated pharmacodynamic response in the rabbit. There was no indication of a teratogenic effect.

There are no long-term animal toxicity or carcinogenicity studies involving macrogol 3350, although there are toxicity studies using high levels of orally administered high molecular weight macrogols that provide evidence of safety at the recommended therapeutic dose.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acesulfame potassium (E950)
Lemon Flavour (contains acacia gum (E414) and flavouring)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

Reconstituted solution: 24 hours
Store in a refrigerator (2°C - 8°C).

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

Reconstituted product: See section 6.3.

6.5 Nature and contents of container

Sachet: laminate consisting of four layers (inner to outer): low density polyethylene, aluminium, low density polyethylene and paper.
Pack sizes: Boxes of 10, 20, 30, 40, 50, 60, 80, 90, 100, 120, 140, 160, 180 or 200 sachets.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused solution should be discarded within 24 hours.

7 MARKETING AUTHORISATION HOLDER

Clonmel Healthcare Ltd
Waterford Road
Clonmel
Co. Tipperary
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0126/217/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th January 2012

Date of last renewal: 31st January 2014

10 DATE OF REVISION OF THE TEXT

December 2014