SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Movicol® 13.8g sachet, powder for oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet of Movicol contains the following active ingredients:

Macrogol 3350	13.125 g
Sodium bicarbonate	178.5 mg
Sodium chloride	350.7 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
Potassium	5.4 mmol/l
Chloride	53 mmol/l
Bicarbonate	17 mmol/l

For excipients, see Section 6.1

3 PHARMACEUTICAL FORM

Powder for oral solution. Free flowing white powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of chronic constipation. Movicol is also effective in resolving faecal impaction, defined as refractory constipation with faecal loading of the rectum and/or colon.

4.2 Posology and method of administration

Chronic constipation

A course of treatment for constipation with Movicol does not normally exceed two 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 severe chronic or resistant constipation, secondary to multiple sclerosis or Parkinson's disease, or induced by regular constipating medication, in particular opioids and antimuscarinics.

Adults, adolescents and 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 Movicol products are available for children.

Faecal impaction

A course of treatment for faecal impaction with Movicol 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 Movicol 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 two sachets are taken in any one hour.

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

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 ingredients or to any of the excipients.

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) MOVICOL 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 MOVICOL (see section 4.5).

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 MOVICOL (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 no or limited amount of data from the use of MOVICOL in pregnant women. Studies in animals have shown reproductive toxicity (see section 5.3).

Breastfeeding

No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to Macrogol 3350 is negligible

MOVICOL can be used during breast-feeding.

4.7 Effects on ability to drive and use machines

Movicol 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 MOVICOL. Mild diarrhoea usually responds to dose reduction.

The frequency of the adverse effects is not known as it cannot be estimated from the available data.

System Order Class	Adverse Event
Immune system disorders	Allergic reactions, including anaphylaxis, angioedema, dyspnoea, rash, erythema, urticaria and pruritus.
Metabolism and nutrition Disorders	Electrolyte disturbances, particularly hyperkalaemia and hypokalaemia.
Nervous system disorders	Headache.
Gastrointestinal disorders	Abdominal pain, diarrhoea, vomiting, nausea, dyspepsia, abdominal distension, borborygmi, flatulence, anal discomfort.
General disorders and administration site conditions	Peripheral oedema

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, Movicol 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 Movicol 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.

Indirect embryofoetal effects were noted in the rabbit at clinically relevant doses. Treatment caused an increased incidence of malrotated limbs, reduction in foetal and placental weights, reduced foetal viability and abortions at maternally toxic doses**.** The safety margin was 1.1 x the maximum recommended dose for faecal impaction in a 60 kg adult for malrotated limb and 2.9 x below the maximum recommended dose for the remaining findings. Rabbits are sensitive animal test species to the effects of GI acting substances and the studies were conducted under exaggerated conditions with administered high dose volumes. The relevance of these findings to humans is unknown.

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)

Lime and Lemon Flavour*

(Lime and lemon flavour contains the following constituents: acacia solids, maltodextrin, lime oil, lemon oil, citral, citric acid and water).

6.2 Incompatibilities

None are known.

6.3 Shelf life

3 years.

Reconstituted solution: 6 hours.

6.4 Special precautions for storage

Sachet: Do not store above 25°C.

Reconstituted solution: Store at 2-8ºC (in a refrigerator and covered)

6.5 Nature and contents of container

Sachets: laminate consisting of four layers: low density polyethylene, aluminium, low density polyethylene and paper.

Pack sizes: boxes of 2, 6, 8, 10, 20, 30, 50, 60 or 100 sachets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused solution should be discarded within 6 hours.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 00322/0070

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18/12/2005

10 DATE OF REVISION OF THE TEXT

05/05/2011