Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Movicol Chocolate 13.9g sachet, powder for oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet of MOVICOL Chocolate contains the following active ingredients:

Macrogol 3350	13.1250g
Sodium Chloride	0.3507g
Sodium Hydrogen Carbonate	0.1785g
Potassium Chloride	0.0317g

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

Sodium	65 mmol/l
Chloride	51 mmol/l
Potassium	5.4 mmol/l
Hydrogen Carbonate	17 mmol/l

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution

Product imported from the UK:
White to light brown free flowing powder

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of chronic constipation in adults and children above the age of 12. MOVICOL Chocolate 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 Chocolate 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 under 12 years of age: Not recommended. Alternative MOVICOL products are available for children.

Faecal impaction
A course of treatment for faecal impaction with MOVICOL Chocolate 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 under 12 years of age: 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 125ml 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.

If patients develop any symptoms indicating shifts of fluid/electrolytes (e.g. oedema, shortness of breath, increasing fatigue, dehydration, cardiac failure) MOVICOL Chocolate 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 Chocolate (see section 4.5).

4.5 Interaction with other medicinal products and other forms of interaction

Clinical interactions with other drugs have been reported extremely rarely. No specific reactions with individual drugs or classes of drugs have been observed.

Macrogol raises the solubility of medicinal products that are soluble in alcohol and relatively insoluble in water (i.e. substances that have a hydrophilic and a hydrophobic pole in their molecular structure).

There is a possibility that the absorption of other medicinal products could be transiently reduced during use with MOVICOL Chocolate (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

There is no experience of the use of MOVICOL Chocolate during pregnancy and lactation and it should only be used if considered essential by the physician.

4.7 Effects on ability to drive and use machines

MOVICOL Chocolate 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

Macrogols are long linear polymers, also known as polyethylene glycols

Macrogol 3350 acts by virtue of its osmotic action in the gut, which induces a laxative effect. Macrogol 3350 increases the water content and hence 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 (parent product) 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 (parent product) 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, although no tests of its effects on reproduction or genotoxicity have been conducted.

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 macrogols that provide evidence of safety at the recommended therapeutic dose.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acesulfame potassium (E950)
Chocolate flavour:
Maltodextrin (potato)
Gum arabic/acacia gum E414
Vegetable oils and fats (palm/coconut oil)
Propylene glycol E1520
Ethyl alcohol

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the container and outer package of the product as marketed in the country of origin
Reconstituted solution: 6 hours.

6.4 Special precautions for storage

Sachet: Do not store above 25°C.
Reconstituted solution: Store at 2-8°C (in a refrigerator and keep covered).

6.5 Nature and contents of container

Over-labelled outer carton containing sachets
Pack size: 30 sachets

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Any unused solution should be discarded within 6 hours

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/89/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th May 2011

10 DATE OF REVISION OF THE TEXT