Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Movicol Chocolate 13.9 g sachet powder for oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet of Movicol Chocolate contains the following active substances:
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

Excipient(s) with known effect
Movicol Chocolate contains benzyl alcohol 14.1 mg per sachet.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution. 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

Posology

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 older people: 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 older people: 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 (see section 4.4 for warning about excipients).

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

4.4 Special warnings and precautions for use

The fluid content of Movicol Chocolate when re-constituted with water does not replace regular fluid intake and adequate fluid intake must be maintained.
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).
Movicol Chocolate contains 14.1 mg benzyl alcohol per sachet. Benzyl alcohol may cause anaphylactoid reactions.
High volumes of benzyl alcohol should be used with caution and only if necessary, especially in subjects with kidney or liver impairment and during pregnancy/ breast feeding because of the risk of accumulation and toxicity (metabolic acidosis) of benzyl alcohol.

This medicinal product contains 186.87 mg (8.125 mmol) sodium per dose, equivalent to 9.3% of the WHO recommended maximum daily intake for sodium. When used for long term constipation the maximum daily dose of this product is equivalent to 28% of the WHO recommended maximum daily intake for sodium. Movicol Chocolate is considered high in sodium. This should be particularly taken into account for those on a low salt diet.
In patients with swallowing problems, who need the addition of a thickener to solutions to enhance an appropriate intake, interactions should be considered, 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. Therefore, other medicines should not be taken orally for one hour before, during and for one hour after taking Movicol Chocolate.

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

4.6 Fertility, pregnancy and lactation

Pregnancy
There are limited amount of data from the use of MOVICOL 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.
MOVICOL can be used during pregnancy.

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.

Fertility
There are no data on the effects of MOVICOL 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

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 Organ Class	Adverse Event
Immune system disorders	Allergic reactions, including anaphylactic reaction, dyspnoea, and skin reactions (see below)
Skin and subcutaneous tissue disorders	Allergic skin reactions including angioedema, urticaria, pruritus, rash, erythema.
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 and anorectal discomfort.
General disorders and administration site conditions	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 Website: www.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
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, 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 foetal and placental weights, reduced foetal 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 Movicol 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 long-term animal toxicity and carcinogenicity studies involving macrogol 3350. Results from these and other toxicity studies using high levels of orally administered high molecular weight macrogols provide evidence of safety at the recommended therapeutic dose.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acesulfame Potassium (E950)
Chocolate Flavour (contains maltodextrin, acacia gum E414, vegetable oils and fats, propylene glycol E1520, and ethyl alcohol)

6.2 Incompatibilities

None are known.

6.3 Shelf life

3 years
Reconstituted solution: 6 hours.

6.4 Special precautions for storage

Sachet: This medicinal product does not require any special storage conditions.
Reconstituted solution: Store at 2°C – 8°C (in a refrigerator and keep covered).

6.5 Nature and contents of container

This product is available in rectangular sachets and tubular (stick-pack) sachets.

Sachet: laminate consisting of four layers: low density polyethylene, aluminium, low density polyethylene and paper.
Pack sizes: boxes of 20 or 30 sachets.
Not all sachets and pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused solution should be discarded within 6 hours.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

6.6 Special precautions for disposal and other handling

Any unused solution should be discarded within 6 hours.

7 MARKETING AUTHORISATION HOLDER

Norgine Healthcare B.V.
Antonio Vivaldistraat 150
Amsterdam
1083HP
Netherlands

8 MARKETING AUTHORISATION NUMBER

PA23265/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th November 2008

Date of last renewal: 20th August 2013

10 DATE OF REVISION OF THE TEXT

April 2023