Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Movicol Ready to Take 13.9 g/25 ml oral solution in sachet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 25 mL sachet of Movicol Ready to Take contains the following active substances:

Macrogol 3350	13.125 g
Sodium chloride	0.3508 g
Sodium hydrogen carbonate	0.1786 g
Potassium chloride	0.0502 g

The concentration of electrolyte ions present in each 25 mL sachet is as follows:

Sodium	325 mmol/L
Chloride	267 mmol/L
Potassium	27 mmol/L
Hydrogen carbonate	85 mmol/L

This corresponds to the following amount of each electrolyte in each 25 mL dose:

Sodium	8.125 mmol
Chloride	6.675 mmol
Potassium	0.675 mmol
Hydrogen carbonate	2.125 mmol

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution in sachet
Clear, colourless to light yellow, free flowing liquid

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of constipation in adults and adolescents (12 years and above).
Movicol Ready to Take 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

Movicol Ready to Take should be used directly from the sachet. This product does not need to be diluted with water.

Chronic Constipation
A course of treatment for constipation with Movicol Ready to Take 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 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 (below 12 years old): Not recommended. Alternative Movicol products are available for children.

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

Faecal Impaction
It is recommended that patients using Movicol Ready to Take for faecal impaction take an additional 1.0 litre of fluid per day. A course of treatment for faecal impaction with Movicol Ready to Take 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 (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 faecal impaction.

It is recommended to drink sufficient amounts of fluids (generally 2.0 to 2.5 litres daily) to maintain good health.

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 Ready to Take 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.

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 Ready to Take 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 Ready to Take (see section 4.5).

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 Ready to Take 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 starch-based food 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

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 Ready to Take (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 Ready to Take.
Movicol Ready to Take 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 Ready to Take 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 Ready to Take 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 Ready to Take 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 Ready to Take. Mild diarrhoea usually responds to dose reduction.

The frequency of the adverse events for Movicol Ready to Take is not known as it cannot be estimated from the available data. The list of adverse events is based on the current Movicol range of products.

System Organ Class	**Adverse Event**
Immune system disorders	Allergic reactions, including anaphylactic reactions, 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, 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 events via HPRA Pharmacovigilance Website: www.hpra.ie.

4.9 Overdose

Severe abdominal 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 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 defecation.

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 (13.8g) (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 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 of powdered Movicol a day (one sachet of powdered Movicol is equivalent to one sachet of Movicol Ready to Take), 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

Sucralose
Purified Water
Strawberry Banana Flavouring containing natural flavouring substances (including extracts from strawberry and banana fruit), flavouring preparations (including celery) and propylene glycol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 30°C.
Do not refrigerate or freeze.

6.5 Nature and contents of container

Sachets composed of polyethylene terephthalate, aluminium and polyethylene.
Pack sizes: boxes of 10, 20, 30 and 50 sachets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA23265/002/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd September 2016

Date of last renewal: 27th April 2021

10 DATE OF REVISION OF THE TEXT

March 2023