SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

MOVICOL Ease 13.7g powder for oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet of Movicol Ease contains the following active substances:

Macrogol 3350	13.1250 g
Sodium Chloride	0.3508 g
Sodium Hydrogen Carbonate	0.1786 g
Potassium Chloride	0.0502 g

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
Potassium	5.4 mmol/l
Hydrogen Carbonate	17 mmol/l

3 PHARMACEUTICAL FORM

Powder for oral solution. Free flowing white powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of occasional constipation.

4.2 Posology and method of administration

Posology

Do not use for more than 5 days. If constipation needs treatment for longer than 5 days, a doctor or pharmacist should be consulted.

As for all laxatives, prolonged use is not recommended.

Adults 18 years and over: 1-3 sachets daily in divided doses, according to individual response. Once regularity in bowel movements has been restarted, dosage should be reduced and treatment can usually be stopped.

Children (below 18 years old): Not recommended. Alternative Movicol products are available for children.

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

Method of administration

Each sachet should be dissolved in 125ml 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.

4.4 Special warnings and precautions for use

Movicol Ease should not be used in children or adolescents under the age of 18 years.

Prolonged excessive use may lead to fluid and electrolyte imbalance and hypokalaemia. Patients with kidney disorders should be aware of possible electrolyte imbalance.

Intestinal loss of fluids may promote dehydration. Symptoms may include thirst and oliguria. In patients suffering from fluid loss where dehydration may be harmful (e.g. renal insufficiency, elderly patients) Movicol Ease should be discontinued and only be restarted under medical supervision.

Like all laxatives, Movicol Ease should not be taken by patients suffering from faecal impaction and undiagnosed, acute or persistent gastro-intestinal complaints, e.g. abdominal pain, nausea and vomiting, unless advised by a doctor, because these symptoms can be sign of potential or existing intestinal blockage (ileus).

Do not exceed the stated dose.

The fluid content of Movicol Ease when re-constituted with water does not replace regular fluid intake and adequate fluid intake must be maintained.

Mild adverse drug reactions are possible as indicated in Section 4.8. If patients develop any symptoms indicating shifts of fluid/electrolytes, (e.g. oedema, shortness
of breath, increasing fatigue, dehydration, cardiac failure), Movicol Ease should be stopped immediately, medical advice should be sought, electrolytes should be 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 Ease (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 long term for constipation, the maximum daily dose of this product is equivalent to 28% of the WHO recommended maximum daily intake for sodium. Movicol Ease 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

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 Ease (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 Ease.

Movicol Ease may result in a potential interactive effect if used with starch-based food thickeners. The 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 Ease 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 Ease 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 Ease can be used during breast-feeding.

Fertility

There are no data on the effects of Movicol Ease 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 Ease 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 Ease. 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 Yellow Card Scheme Website www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

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.

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

None

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 2ºC – 8ºC (in a refrigerator and covered).

6.5 Nature and contents of container

This product is available in tubular (stick-pack) sachets.
Each sachet contains 13.7 g of powder.

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

Pack sizes: boxes of 10 and 20 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.

7 MARKETING AUTHORISATION HOLDER

Norgine Pharmaceuticals Limited

ARC Uxbridge, Building 01,

Sanderson Road,

Uxbridge,

UB8 1DH, UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 20011/0077

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

13/03/2024

10 DATE OF REVISION OF THE TEXT

08/04/2025