New Zealand Datasheet

1 PRODUCT NAME
MOVICOL Lemon-Lime Flavour (macrogol 3350 13.125 g and electrolytes) powder for oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each sachet of MOVICOL Lemon-Lime Flavour contains:

Macrogol 3350	13.125 g
Sodium chloride	350.7 mg
Sodium bicarbonate	178.5 mg
Potassium chloride	46.6 mg

Contains sodium. For full list of excipients, see 6.1 List of excipients.

3 PHARMACEUTICAL FORM
Sachets containing free-flowing white powder for oral solution.

The content of electrolyte ions per sachet when made up to 125 mL is:

Sodium	65 mmol/L
Potassium	5.4 mmol/L
Chloride	53 mmol/L
Bicarbonate	17 mmol/L

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
For effective relief from constipation, treatment of chronic constipation. MOVICOL Lemon-Lime Flavour is also effective in resolving faecal impaction, defined as refractory constipation with faecal loading of the rectum and/or colon confirmed by physical examination of abdomen and rectum.

4.2 Dose and method of administration
Constipation: The dose is 1 sachet daily. This may be increased to 2-3 sachets daily, if required.

Faecal Impaction: 8 sachets daily, consumed within 6 hours. A course of treatment for faecal impaction does not normally exceed 3 days.

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
For oral administration. Each sachet should be dissolved in 125 mL water. For faecal impaction 8 sachets may be dissolved in 1 litre of water. Store the solution refrigerated and discard any solution not used within 6 hours.

Also see Section 4.4 Special Warnings and Precautions for use.

4.3 Contraindications

Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, ileus and severe inflammatory conditions of the intestinal tract, such as Crohn's disease, ulcerative colitis and toxic megacolon.

Known hypersensitivity to the active substance or any of the excipients.

4.4 Special warnings and precautions for use

The fluid content of MOVICOL Lemon-Lime Flavour when re-constituted with water does not replace regular fluid intake and adequate fluid intake must be maintained.

Adverse reactions are possible as described 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 Lemon-Lime Flavour 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 a decrease in gastro-intestinal transit time induced by MOVICOL Lemon-Lime Flavour (see section 4.5).

This medicinal product contains 187 mg of sodium per sachet, equivalent to 9.3% of the Suggested Dietary Target (SDT) for sodium of 2,000 mg/day for adults. The maximum daily dose of this product for constipation is equivalent to 28% of the SDT for sodium. MOVICOL Lemon-Lime Flavour is considered high in sodium. This should be particularly taken into account for those on a low salt diet.

As with all laxatives prolonged use is not usually recommended and may lead to dependence. If prolonged use is necessary, it should only be under medical supervision. Extended use may be necessary in the care of patients with severe chronic or resistant constipation, secondary to multiple sclerosis or Parkinson's Desease, or induced by regular constipating medication, in particular opioids and antimuscarinics. Patients should be advised to drink plenty of water and increase fibre in the diet, except in the case of medication-induced constipation.

Use in Children

Macrogol 3350 paediatric dosage (MOVICOL Junior) is recommended for use in children aged 2 years and above.

4.5 Interaction with other medicines and other forms of interaction

There is a possibility that the absorption of other medicinal products could be transiently reduced during use with MOVICOL Lemon-Lime Flavour (see above). There have been isolated reports of decreased efficacy with some concomitantly administered medicinal products, e.g. anti- epileptics. A theoretical potential also exists for decreased absorption (rate and extent) of drugs which are generally poorly absorbed or are contained in sustained or modified release dosage forms. This is more likely to occur if MOVICOL Lemon-Lime Flavour is overdosed to induce watery diarrhoea.

MOVICOL Lemon-Lime Flavour may have a potential interactive effect when used with starch-based food thickeners. The polyethylene glycol (PEG) 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

For MOVICOL Lemon-Lime Flavour a limited amount of clinical data on exposed pregnancies are available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or post-natal development.

No effects during pregnancy are anticipated, since systemic exposure to macrogol 3350 is negligible. MOVICOL Lemon-Lime Flavour can be used during pregnancy.

Breast feeding

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

MOVICOL Lemon-Lime Flavour can be used during breast-feeding.

Fertility

No data available.

4.7 Effects on ability to drive and use machines

None known.

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 Lemon-Lime Flavour. Diarrhoea usually responds to dose reduction.

System Order 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, pruritis, 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 medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions via https://nzphvc.otago.ac.nz/reporting/.

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.

In case of accidental overdosage, symptomatic treatments and supportive care are suggested. For information on the management of overdose, contact the National Poisons Centre on 0800 POISON (0800 764 766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Osmotically acting laxatives, ATC Code: A06AD

Macrogol 3350 exerts an 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.

The laxative action of macrogol has a time course, which will vary according to the severity of the constipation being treated. Faecal Impaction – In a non-comparative study in 27 adult patients, MOVICOL Lemon-Lime Flavour cleared the faecal impaction in 12/27 (44%) after 1 day's treatment, 23/27 (85%) after 2 day's treatment and 24/27 (89%) at the end of 3 days. Controlled comparative studies have not been performed with other treatments (e.g. enemas).

5.2 Pharmacokinetic properties

Macrogol 3350 is unchanged along the gut. It is virtually unabsorbed from the gastrointestinal tract. Any macrogol 3350 that is absorbed is excreted via the urine.

5.3 Preclinical safety data

Preclinical studies show that macrogol 3350 has no significant systemic toxicity potential.

6 PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Contains a lime and lemon flavour and potassium acesulfame as a sweetener.

6.2 Incompatibilities

None are known.

6.3 Shelf life

3 years (36 months).

6.4 Special precautions for storage

Sachet: Store below 25ºC.
Solution: Store at 2-8ºC (in refrigerator and covered) and discard any solution not used within 6 hours.

6.5 Nature and contents of container
Boxes of 8, 20 or 30 sachets each containing 13.125 g of macrogol 3350.

6.6 Special precautions for disposal
No special precautions required.

7 MEDICINE SCHEDULE
General Sale Medicine.

8 SPONSOR
Sponsor:
CARSL Consulting
PO Box 766
Hastings
Ph (06) 844 4490

for Norgine Pty Limited

Distributor:
Norgine Pty Limited
C/- Pharmacy Retailing (NZ) Ltd
Trading as Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks
Auckland
Telephone: (09) 918 5100
Fax: (09) 918 5101

9 DATE OF FIRST APPROVAL
3 December 1998

10 DATE OF REVISION OF THE TEXT
30 June 2020

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
4.5	Added: MOVICOL Lemon-Lime Flavour may have a potential interactive effect when used with starch-based food thickeners. The polyethylene glycol (PEG) ingredient counteracts the thickening effect of starch, effectively liquefying preparations that need to remain thick for people with swallowing problems.