AUSTRALIAN PRODUCT INFORMATION – MOVICOL® READY TO TAKE (MACROGOL 3350 AND ELECTROLYTES) ORAL SOLUTION

1 NAME OF THE MEDICINE

Macrogol 3350 and electrolytes (sodium chloride, sodium bicarbonate, potassium chloride).

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 25 mL of MOVICOL Ready To Take oral solution contains:

Macrogol 3350	13.125 g
Sodium chloride	350.8 mg
Sodium bicarbonate	178.6 mg
Potassium chloride	50.2 mg

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

Sodium	325 mmol/L
Chloride	267 mmol/L
Potassium	27 mmol/L
Bicarbonate	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
Bicarbonate	2.125 mmol

Excipient with known effect: Sucralose.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Oral Solution.
A clear colourless to light yellow, free flowing liquid.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

For use in adults and children over 12 years of age for effective relief from constipation and treatment of chronic constipation.

4.2 DOSE 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.

The fluid content of MOVICOL Ready to Take does not replace regular fluid intake and adequate fluid intake must be maintained. It is recommended that patients drink a glass of water or other fluid after taking MOVICOL Ready To Take.

Adults and children 12 years and older
Constipation: One sachet of MOVICOL Ready To Take once daily. This may be increased to 2 – 3 sachets daily, if required according to individual response.

Children under 12 years of age
MOVICOL Ready To Take is not recommended for use in children below the age of 12 years (see Section 4.4 Special warnings and precautions for use). Alternative MOVICOL products are available for children.

Patients with impaired cardiovascular function
No more than two sachets should be taken in any one hour.

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

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 macrogol or any of the ingredients.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Adverse reactions are possible as described under Section 4.8 Adverse Effects (Undesirable Effects). If patients develop any symptoms indicating shifts of fluid/electrolytes (eg. 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 medicines could transiently be reduced due to a decrease in gastro-intestinal transit time induced by MOVICOL Ready To Take (see Section 4.5 Interactions with other medicines and other forms of interactions).

This medicinal product contains 187 mg of sodium per sachet, equivalent to 9.3% of the WHO recommended maximum daily intake of 2g sodium for an adult. The maximum daily dose of this product for constipation (ie. 3 sachets) 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.

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 Disease, or induced by regular constipating medication, in particular opioids and antimuscarinics. Patients should be advised to drink plenty of water. They should also increase fibre in the diet, except in the case of medication-induced constipation.

Use in the elderly
No data available.

Paediatric use
Not recommended. Alternative MOVICOL products are available for children.

Effects on laboratory tests
No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

There is a possibility that the absorption of other medicines could be transiently reduced during use with MOVICOL Ready To Take (see Section 4.4 Special warnings and precautions for use). 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 Ready To Take is overdosed to induce watery diarrhoea.

MOVICOL Ready To Take may have a potential interactive effect when 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

Effects on fertility
No data available

Use in pregnancy
Pregnancy Category B1: Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus having been observed. Studies in animals have not shown evidence of an increased occurrence of foetal damage.

There were no direct embryotoxic or teratogenic effects in rats at maternally toxic doses up to 40 g/kg/day, 51x the maximum recommended dose in humans for chronic constipation.

Indirect effects, including reduction in fetal and placental weights, reduced fetal viability and abortions, were noted in the rabbit at doses below the maximum recommended human dose. Rabbits are particularly sensitive to the effects of GI acting substances, and the findings are considered most likely a reflection of poor maternal condition as a result of an exaggerated pharmacodynamic response rather than direct embryofetal toxicity. There was no indication of a teratogenic effect.

Use in lactation

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.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

MOVICOL Ready To Take has no influence on the ability to drive or use machines.

4.8 ADVERSE EFFECTS (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. 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).
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.
Skin and subcutaneous tissue disorders	Allergic skin reactions including angioedema, urticaria, pruritus, rash, erythema.

Reporting suspected adverse effects
Reporting suspected adverse reactions after registration 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 at www.tga.gov.au/reporting-problems in Australia.

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. For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

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.

Clinical Trials

No data available.

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

Genotoxicity

Preclinical studies provide evidence that macrogol 3350 has no significant systemic toxicity potential, based on conventional studies of pharmacology, repeated dose toxicity, genotoxicity and toxicity to reproduction.

Carcinogenicity

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

MOVICOL Ready To Take oral solution also contains sucralose (E955), purified water, and strawberry-banana flavour, which contains natural flavouring substances, flavouring preparations (including celery oil) and propylene glycol.

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 30°C. Do not refrigerate or freeze.

6.5 NATURE AND CONTENTS OF CONTAINER

MOVICOL Ready To Take is a liquid for oral solution that does not require dilution before use. It is supplied in 25 mL sachets, in boxes of 10, 20, 30 and 50 sachets.

Not all pack sizes may be marketed.

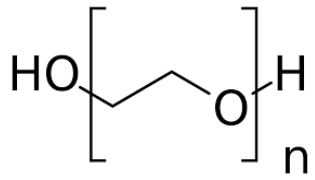
6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical structure

Macrogol 3350



Sodium chloride	NaCl
Sodium bicarbonate	$NaHCO_3$
Potassium chloride	KCl

CAS number

Macrogol 3350	25322-68-3
Sodium chloride	7647-14-5
Sodium bicarbonate	144-55-8
Potassium chloride	7447-40-7

7 MEDICINE SCHEDULE (POISONS STANDARD)

Unscheduled

8 SPONSOR

Norgine Pty Ltd
Suite 3.01 Building A
20 Rodborough Road
Frenchs Forest NSW 2086

9 DATE OF FIRST APPROVAL

3 May 2016

10 DATE OF REVISION

29 October 2020

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
4.5	Added text "MOVICOL Ready To Take may have a potential interactive effect when 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."