MOVICOL® Liquid
Orange Flavour
Concentrate for Oral Solution (macrogol 3350)

NAME OF THE MEDICINE:
MOVICOL Liquid Orange Flavour, Concentrate for Oral Solution.

DESCRIPTION:
A clear colourless solution.
Each 25 mL of MOVICOL Liquid concentrate for oral solution contains:

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

The concentration of electrolyte ions when 25 mL is made up with water to 125 mL is:

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

MOVICOL Liquid Concentrate for oral solution also contains sucralose (E955), orange flavour (contains ethanol), acesulfame potassium (E950), water, and the following preservatives; benzyl alcohol 45.6mg per 25 mL, methyl hydroxybenzoate (E218) 11.3 mg per 25 mL, ethyl hydroxybenzoate (E214) 5.6 mg per 25 mL.

PHARMACOLOGY:
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.

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.

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 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 (eg. enemas).

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

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.

PRECAUTIONS:
The fluid content of MOVICOL Liquid when re-constituted with water does not replace regular fluid intake and adequate fluid intake must be maintained.

Adverse reactions are possible as described under *Adverse Reactions.* If patients develop any symptoms indicating shifts of fluid/electrolytes (eg. oedema, shortness of breath, increasing fatigue, dehydration, cardiac failure) MOVICOL Liquid 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 Liquid (see interactions with other drugs).

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.

MOVICOL Liquid contains benzyl alcohol (45.6 mg / 25 mL); if extended treatment is required for the management of constipation the maximum recommended dose of 3 times 25 mL dose per day should not be exceeded.

Use in 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 fetus having been observed. Studies in animals have not shown evidence of an increased occurrence of fetal 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 and 19x for faecal impaction.

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 Liquid can be used during breast-feeding.

Use in children: This product contains 45.6 mg of benzyl alcohol in each diluted dose of 125 mL. The maximum recommended daily dose of the product for constipation contains 136.8 mg of benzyl alcohol, and for faecal impaction contains 364.8 mg benzyl alcohol. This product should not be used in children 12 years of age or under because the safety of these amounts of benzyl alcohol in this age group has not been established. Alternative MOVICOL products are available for children.

Mutagenicity and carcinogenicity:
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.

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.

INTERACTIONS WITH OTHER MEDICINES:
There is a possibility that the absorption of other medicines could be transiently reduced during use with MOVICOL Liquid (see Precautions). 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 Liquid is overdosed to induce watery diarrhoea.

ADVERSE REACTIONS:
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 Liquid. 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.

DOSAGE AND ADMINISTRATION:
The product must not be taken undiluted and may only be diluted in water. Measure 25 mL of MOVICOL Liquid with the 25 mL measuring cup provided, then add this to 100 mL of water. Any unused diluted solution should be discarded within 24 hours.

Adults:
Constipation: 25 mL of MOVICOL Liquid added to 100 mL of water once daily (to make a total volume of 125 mL). This may be increased to 2 – 3 doses of 25 mL daily (each 25 mL dose added to 100 mL of water), if required according to individual response.

Faecal Impaction: 8 doses of 25 mL daily (each 25 mL dose added to 100 mL of water). A course of treatment for faecal impaction does not normally exceed 3 days.

Children:
MOVICOL Liquid is not recommended for use in children below the age of 12 years (see PRECAUTIONS). 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 doses are taken in any one hour.

Patients with renal insufficiency: No dosage change is necessary for treatment of either constipation or faecal impaction.

OVERDOSAGE:
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)

PRESENTATION AND STORAGE CONDITIONS:
MOVICOL Liquid is a liquid concentrate for oral solution that requires dilution before use. Each 25 mL contains 13.125 g of macrogol 3350 and electrolytes.
It is supplied in a 500 mL plastic bottle, with a clear plastic 25 mL measuring cup.
Store below 30°C. Any diluted solution should be discarded after 24 hours.

NAME AND ADDRESS OF SPONSOR:
Norgine Pty Ltd. 3/14 Rodborough Road, Frenchs Forest NSW 2086.

POISON SCHEDULE
MOVICOL Liquid is a PHARMACY MEDICINE (S2).

DATE OF FIRST INCLUSION IN THE ARTG:
11 July 2013 AUST R 212114

DATE OF MOST RECENT AMENDMENT:
15 July 2015