AUSTRALIAN PRODUCT INFORMATION – MOVICOL® JUNIOR FLAVOUR FREE (MACROGOL 3350 AND ELECTROLYTES) POWDER FOR SOLUTION

1 NAME OF THE MEDICINE

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

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet of MOVICOL Junior Flavour Free powder contains:

Macrogol 3350	6.563 g
Sodium chloride	175.4 mg
Sodium bicarbonate	89.3 mg
Potassium chloride	25.1 mg

The content of electrolyte ions per sachet when made up to 62.5 mL is:

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

3 PHARMACEUTICAL FORM

Powder for oral solution.
Free flowing white powder.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

For effective relief of constipation in adults. For treatment of chronic constipation in adults and children aged 2 years and older. For resolving faecal impaction, defined as refractory constipation with faecal loading of the rectum, or the rectum and colon, confirmed by physical examination of abdomen and rectum, in adults and children aged 2 years and older. For prevention of recurrence of faecal impaction in children aged 2 years and older. Use in children aged 2 years and older should be limited to 12 weeks except under medical supervision.

4.2 DOSE AND METHOD OF ADMINISTRATION

Adults and children over 12 years

Constipation: The dose is 2 sachets daily and may be increased up to 6 sachets daily if required. For chronic constipation the dose may be reduced to 1 sachet daily according to individual response.

For patients of 12 years and older using 2 sachets daily or more, it is recommended to use MOVICOL Flavour Free (full strength).

Faecal Impaction: 16 sachets daily, all of which should be consumed within 6 hours. A course of treatment for faecal impaction does not normally exceed 3 days.
For patients of 12 years and older it is recommended to use MOVICOL.

Children 2 years and older

Chronic constipation and prevention of recurrence of faecal impaction
Children aged 2-5 years: The usual starting dose is 1 sachet daily.
Children 6-11 years: The usual starting dose is 2 sachets daily.

The dose should be adjusted up or down as required to produce regular soft stools. The maximum dose does not normally exceed 4 sachets a day.

Use in children aged 2 years and older should be limited to 12 weeks except under medical supervision.

MOVICOL Junior Flavour Free is not recommended for children below 2 years of age.

Faecal Impaction
Children 2-11 years: A course of treatment for faecal impaction with MOVICOL Junior Flavour Free is for up to 7 days as follows:

	NUMBER OF MOVICOL JUNIOR FLAVOUR FREE SACHETS						
Age (years)	**Day 1**	**Day 2**	**Day 3**	**Day 4**	**Day 5**	**Day 6**	**Day 7**
2- 5	**2**	**4**	**4**	**6**	**6**	**8**	**8**
6-11	**4**	**6**	**8**	**10**	**12**	**12**	**12**

The above dosage regimen should be stopped once disimpaction has occurred. An indicator of disimpaction is the passage of a large volume of stools. After disimpaction, it is recommended that the child follows an appropriate bowel management programme to prevent reimpaction.

MOVICOL Junior Flavour Free is not recommended for children under 2 years of age.

Patients with impaired cardiovascular function

Adults and children over 12 years

For the treatment of faecal impaction the dose should be divided so that no more than four sachets are taken in any one hour.

Children (2-11 years)

There are no clinical data for this group of patients, therefore MOVICOL Junior Flavour Free is not recommended for use in this patient group.

Patients with renal insufficiency

Adults and children over 12 years

No dosage change is necessary for treatment of either constipation or faecal impaction.

Children (2-11 years)

There are no clinical data for this group of patients**,** therefore MOVICOL Junior Flavour Free is not recommended for use in this patient group.

Also see Section 4.4 Special Warnings and Precautions for use.

Administration

For oral administration. Each sachet should be dissolved in ¼ cup (about 60 mL) water. For use in faecal impaction the correct number of sachets can be reconstituted in advance and kept covered and refrigerated for 24 hours. For example 12 sachets can be made up into 750 mL of water and 16 sachets into one litre of water.

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

The fluid content of MOVICOL Junior Flavour Free 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 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 Junior Flavour Free 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 Junior Flavour Free (see 4.5 Interactions with other medicines and other forms of interactions).

MOVICOL Junior Flavour Free contains 93.4 mg sodium per sachet. This is equivalent to 4.6% of the WHO recommended maximum daily intake of 2g sodium for an adult. The maximum daily dose of this product for constipation (ie. 6 sachets in adults and children over 12 years) is equivalent to 28% of the WHO recommended maximum daily intake for sodium. MOVICOL Junior Flavour Free 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. 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
The safety and efficacy of MOVICOL Junior Flavour Free in the treatment of chronic constipation in children under two years of age has not been established.

Chronic constipation in children
Constipation is the less-frequent-than-usual passage of large, firm or hard stools. Most normal children will occasionally experience constipation, which will normally require no more than a healthy diet, plenty of exercise, regular toilet use and, sometimes, occasional use of laxatives. However, a small proportion of children will pass stools less frequently than 3 times per week, with excessive straining and discomfort or pain at these times. For these children a supervised plan of treatment over a period of at least 6 – 12 months, utilising a product such as MOVICOL Junior, Flavour Free to restore normal patterns of toilet use and stool formation may be considered appropriate. However, safety and efficacy of MOVICOL Junior Flavour Free has only been proved for a period of up to three months. Treatment should be stopped gradually and resumed if constipation recurs.

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 Junior Flavour Free (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 Junior Flavour Free is overdosed to induce watery diarrhoea.

MOVICOL Junior Flavour Free 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 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 Junior Flavour Free can be used during breast-feeding.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

MOVICOL Junior Flavour Free has no influence on the ability to drive and 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 Junior Flavour Free. 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 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

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.

In a non-comparative study in 63 children, MOVICOL cleared the faecal impaction in 92% of patients within 3-7 days of treatment (median 6 days). For the 2-4 years age group, the average total number of sachets required was equivalent to 28.6 MOVICOL Junior Flavour Free sachets, and for the 5-11 age group the average total number of sachets required was equivalent to 47.2 MOVICOL Junior Flavour Free sachets.

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

None.

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 25°C.

6.5 NATURE AND CONTENTS OF CONTAINER

Boxes of 30 sachets. Each sachet contains 6.9 g powder.

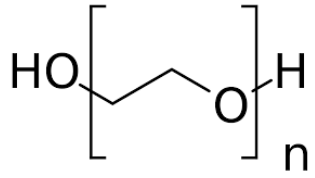
6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

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

18 March 2009

10 DATE OF REVISION

29 October 2020

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
4.5	Added text "MOVICOL Junior Flavour Free 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."