# New Zealand Datasheet

## 1 PRODUCT NAME
MOVICOL® Junior Lemon-Lime Flavour
Macrogol 3350 plus electrolytes Oral Powders for Solution

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each sachet of MOVICOL Junior contains:

| | |
|---|---|
| Macrogol 3350 | 6.563 g |
| Sodium chloride | 175.4 mg |
| Sodium bicarbonate | 89.3 mg |
| Potassium chloride | 23.3 mg |

MOVICOL Junior also contains a lime and lemon flavour and potassium acesulfame as a sweetener.

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

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

## 3 PHARMACEUTICAL FORM
MOVICOL Junior is a free-flowing white oral powder for solution.

## 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.

**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 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 is for up to 7 days as follows:

| | **Number of MOVICOL Junior 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 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 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 is not recommended for use in this patient group.

**Administration**
For oral administration.

Each sachet should be dissolved in ¼ cup (approx 60ml) of 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 750ml 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 the active substance or any of the excipients.

## 4.4 Special warnings and precautions for use
The fluid content of MOVICOL Junior 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 Junior 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 Junior (see section 4.5).

As with all laxatives prolonged use is undesirable and may lead to dependence. Patients should be advised to drink plenty of water and increase fibre in the diet, except in cases of medication-induced constipation.

**Use in Children**
The safety and efficacy of MOVICOL Junior in the treatment of chronic constipation in children under two years of age has not been established.

<u>Chronic constipation in children:</u>

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, to restore normal patterns of toilet use and stool formation may be considered appropriate.

## 4.5 Interaction with other medicines and other forms of interaction

There is a possibility that the absorption of other medicinal products could be reduced during use with MOVICOL Junior (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 Junior is overdosed to induce watery diarrhoea.

## 4.6 Fertility, pregnancy and lactation

**Pregnancy**

For MOVICOL, 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 Junior 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 Junior can be used during breast-feeding.

## 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 Junior. 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 |
| 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 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 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 sachets, and for the 5-11 age group the average total number of sachets was equivalent to 47.2 MOVICOL Junior sachets.

## 5.2 Pharmacokinetic properties
Macrogol 3350 is unchanged along the gut. It is virtually unabsorbed from the gastrointestinal tract and has no known pharmacological activity. 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

Acesulfame potassium, Lemon & Lime Trusil 463842.

## 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 2-8ºC (in refrigerator and covered).

## 6.5 Nature and contents of container

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

## 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) 875 0979

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 March 2015

# 10 DATE OF REVISION OF THE TEXT

14 January 2019
CCDS V6 2014

# SUMMARY TABLE OF CHANGES

| Section changed | Summary of new information |
|---|---|
| All | Product name changed |
| 4.8 | Reporting of adverse events added |
| 4.9 | Poisons number added |
| 8 | Update Sponsor's details |