MOVICOL® Junior
Powder for Solution (macrogol 3350)

Product Name:
MOVICOL Junior

Product Description:
Each sachet of MOVICOL Junior 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

Pharmacology:
Macrogol 3350 acts by virtue of its osmotic effect 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.

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.

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 required was equivalent to 47.2 MOVICOL Junior sachets.

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.

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 any of the ingredients.

Precautions:
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 under *Adverse Reactions.* If patients develop any symptoms indicating shifts of fluid/electrolytes (eg. 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 Interactions with other drugs).

As with all laxatives, prolonged use is undesirable 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 medication-induced constipation.

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 Junior can be used during breast-feeding.

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.

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, to restore normal patterns of toilet use and stool formation may be considered appropriate. However, safety and efficacy of MOVICOL Junior has only been proved for a period of up to three months. Treatment should be stopped gradually and resumed if constipation recurs.

Interactions with other drugs:
There is a possibility that the absorption of other medicinal products could be transiently reduced during use with MOVICOL Junior. 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.

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.

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 Junior. Diarrhoea usually responds to a 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:
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 (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.

Overdosage:
Severe pain or distention 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.

Presentation:
Powder for solution. Boxes of 30 sachets. Each sachet contains 6.9 g of powder. AUST R 160225.

Storage:
Store below 25°C

NORGINE

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