

# New Zealand Datasheet

## Name of Medicine

### MOVICOL-Half

Macrogol 3350 plus electrolytes

## Presentation

MOVICOL-Half is a free flowing white powder. Each sachet of MOVICOL-Half contains:

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

MOVICOL-Half 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

## Uses

### Actions

ATC code: A06A D

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

## **Pharmacokinetics**

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.

## **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.

## **Dosage and 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-Half 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-Half is

for up to 7 days as follows:

	Number of MOVICOL-Half 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-Half 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-Half 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-Half 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.

## **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 excipients.

## **Warnings and Precautions**

Mild adverse reactions are possible as described under *Adverse Effects*. If patients develop any symptoms indicating shifts of fluid/electrolytes (eg. oedema, shortness of breath, increasing fatigue, dehydration, cardiac failure) MOVICOL-Half should be stopped immediately and electrolytes measured, and any abnormality should be treated appropriately.

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.

## **Mutagenicity and Carcinogenicity**

Preclinical studies show that macrogol 3350 has no significant systemic toxicity potential, although no tests of its genotoxicity have been conducted.

## **Use in Pregnancy and Lactation**

There is no experience of the use of MOVICOL-Half during pregnancy and lactation. No preclinical tests of its effects on reproduction have been conducted.

MOVICOL-Half should only be used if considered essential by the physician.

## **Use in Children**

The safety and efficacy of MOVICOL-Half 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-Half, to restore normal patterns of toilet use and stool formation may be considered appropriate.

## **Effects on Ability to Drive and Use Machines**

None known.

## **Adverse Effects**

Abdominal distention and pain, borborygmi and nausea, attributable to the expansion of the contents of the intestinal tract, can occur. Mild diarrhoea which usually responds to dose reduction, can occur. Other reported undesirable effects in children include perianal inflammation and soreness. Allergic reactions including anaphylaxis are a possibility.

## **Interactions**

No clinical interactions have been reported. Macrogol raises the solubility of drugs that are soluble in alcohol and relatively insoluble in water. There is, therefore, a theoretical possibility that the absorption of such drugs could be transiently reduced. 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-Half is overdosed to induce watery diarrhoea.

## **Overdosage**

Severe pain or distention can be treated by nasogastric aspiration. Extensive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances.

## **Pharmaceutical Precautions**

Sachet: Store below 25°C.

Solution: Store 2-8°C (in refrigerator and covered).

## **Medicine Classification**

General Sale Medicine.

## **Package Quantities**

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

## **Further Information**

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## **Name and Address**

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## **Date of Preparation**

13 May 2009