

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Movicol Paediatric Plain 6.9 g sachet, powder for oral solution.

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet of MOVICOL Paediatric Plain contains the following active ingredients:

Macrogol 3350	6.563 g
Sodium Chloride	175.4 mg
Sodium Hydrogen Carbonate	89.3 mg
Potassium Chloride	25.1 mg

The content of electrolyte ions per sachet when made up to 62.5ml of solution is as follows:

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

For a full list of excipients, see section 6.1

### 3 PHARMACEUTICAL FORM

Powder for oral solution.

*Product imported from UK.*

Free flowing white powder.

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic Indications

For the treatment of chronic constipation in children 2 to 11 years of age.

For the treatment of faecal impaction in children from the age of five years, defined as refractory constipation with faecal loading of the rectum and/or colon.

#### 4.2 Posology and method of administration

##### Chronic constipation

The usual starting dose is 1 sachet daily for children aged 2 to 6 years, and 2 sachets daily for children aged 7 – 11 years. The dose should be adjusted up or down as required to produce regular soft stools.

If the dose needs increasing this is best done every second day. The maximum dose needed does not normally exceed 4 sachets a day.

Treatment of children with chronic constipation needs to be over a prolonged period (at least 6 – 12 months). However, safety and efficacy of MOVICOL Paediatric Plain has only been proved for a period of up to three months. Treatment should be stopped gradually and resumed if constipation recurs.

### **Faecal impaction**

A course of treatment for faecal impaction with MOVICOL Paediatric Plain is for up to 7 days as follows:

#### **Daily dosage regimen:**

<b>Number of MOVICOL Paediatric sachets</b>							
<b>Age (years)</b>	<b>Day 1</b>	<b>Day 2</b>	<b>Day 3</b>	<b>Day 4</b>	<b>Day 5</b>	<b>Day 6</b>	<b>Day 7</b>
<b>5-11</b>	<b>4</b>	<b>6</b>	<b>8</b>	<b>10</b>	<b>12</b>	<b>12</b>	<b>12</b>

The daily number of sachets should be taken in divided doses, all consumed within a 12 hour period. 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 program to prevent reimpaction (dosing for prevention of re-impaction should be as for patients with chronic constipation; see above).

MOVICOL Paediatric Plain is not recommended for children below five years of age for the treatment of faecal impaction, or in children below two years of age for the treatment of chronic constipation. For patients of 12 years and older it is recommended to use MOVICOL.

#### **Patients with impaired cardiovascular function:**

There are no clinical data for this group of patients. Therefore MOVICOL Paediatric Plain is not recommended for treating faecal impaction in children with impaired cardiovascular function.

#### **Patients with renal insufficiency:**

There are no clinical data for this group of patients. Therefore MOVICOL Paediatric Plain is not recommended for treating faecal impaction in children with impaired renal function.

### **Administration**

Each sachet should be dissolved in 62.5 ml (quarter of a glass) of water. The correct number of sachets may be reconstituted in advance and kept covered and refrigerated for up to 24 hours. For example, for use in faecal impaction, 12 sachets can be made up into 750 ml of water.

### **4.3 Contraindications**

Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, ileus, severe inflammatory conditions of the intestinal tract, such as Crohn's disease and ulcerative colitis and toxic megacolon.

Hypersensitivity to the active substances.

#### 4.4 Special warnings and precautions for use

Diagnosis of faecal impaction/faecal loading of the rectum should be confirmed by the physical or radiological examination of the abdomen and rectum.

Rarely symptoms indicating shifts of fluid/electrolytes e.g. oedema, shortness of breath, increasing fatigue, dehydration and cardiac failure have been reported in adults when using preparations containing macrogol. If this occurs MOVICOL Paediatric Plain should be stopped immediately, electrolytes measured, and any abnormality should be treated appropriately.

When used in high doses to treat faecal impaction this medicinal product should be administered with caution to patients with impaired gag reflex, reflux oesophagitis or diminished levels of consciousness.

MOVICOL solution when reconstituted has no calorific value.

The absorption of other medicinal products could transiently be reduced due to an increase in gastro-intestinal transit rate induced by MOVICOL Paediatric Plain (see section 4.5).

#### 4.5 Interaction with other medicinal products and other forms of interaction

Medicinal products in solid dose form taken within one hour of administration of large volumes of macrogol preparations (as used when treating faecal impaction) may be flushed from the gastrointestinal tract and not absorbed.

Macrogol raises the solubility of medicinal products that are soluble in alcohol and relatively insoluble in water.

There is a possibility that the absorption of other medicinal products could be transiently reduced during use with MOVICOL Paediatric Plain (see section 4.4). There have been isolated reports of decreased efficacy with some concomitantly administered medicinal products, e.g. anti-epileptics.

#### 4.6 Fertility, pregnancy and lactation

##### *Pregnancy*

There are no or limited amount of data from the use of MOVICOL in pregnant women. Studies in animals have shown reproductive toxicity (see section 5.3).

##### *Breastfeeding*

No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to Macrogol 3350 is negligible

MOVICOL can be used during breast-feeding.

#### 4.7 Effects on ability to drive and use machines

MOVICOL Paediatric Plain has no influence on the ability to drive and use machines.

#### 4.8 Undesirable effects

The frequency of the adverse reactions listed below is defined using the following convention: very common (>1/10); common (>1/100, <1/10); uncommon (>1/1,000, <1/100); rare (>1/10,000, <1/1,000); and very rare (<1/10,000).

Reactions related to the gastrointestinal tract are the most common to occur. These may include:

##### ***Chronic Constipation Indication***

##### Immune system disorders:

Rare: allergic reactions, including anaphylaxis.

Other symptoms of allergic reactions include pruritus, urticaria and dyspnoea

Gastrointestinal disorders:

Very common: abdominal pain, borborygmi, diarrhoea or loose stools which normally respond to a reduction in dose.

Common: nausea, mild vomiting, abdominal distension, flatulence, perianal inflammation and soreness.

***Faecal Impaction Indication***

Immune system disorders:

Rare: allergic reactions, including anaphylaxis.

Other symptoms of allergic reactions include pruritus, urticaria and dyspnoea

Gastrointestinal disorders:

Very common: mild vomiting, abdominal distension and pain which are attributable to the expansion of the contents of the intestinal tract, perianal inflammation and soreness.

Vomiting may be resolved if the dose is reduced or delayed.

Common: borborygmi, nausea and mild diarrhoea.

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 Paediatric Plain.

## 4.9 Overdose

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

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Osmotically acting laxatives

ATC code: A06A D65

Macrogol 3350 acts by virtue of its 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.

In an open study of MOVICOL in chronic constipation, weekly defaecation frequency was increased from 1.3 at baseline to 6.7, 7.2 and 7.1 at weeks 2, 4 and 12 respectively. In a study comparing MOVICOL and lactulose as maintenance therapy after disimpaction, weekly stool frequency at the last visit was 9.4 (SD 4.46) in the MOVICOL group compared with 5.9 (SD 4.29). In the lactulose group 7 children re-impacted (23%) compared with no children in the MOVICOL group.

For the indication of faecal impaction comparative studies have not been performed with other treatments (e.g. enemas). In a non-comparative study in 63 children, MOVICOL (Paediatric) cleared the faecal impaction in the majority of patients within 3 - 7 days of treatment. For the 5 - 11 years age group the average total number of sachets of MOVICOL Paediatric required was 47.2.

### 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**

Preclinical studies provide evidence that macrogol 3350 has no significant systemic toxicity potential, based on conventional studies of pharmacology, repeated dose toxicity and genotoxicity.

Indirect embryofetal effects were noted in the rabbit at clinically relevant doses. Treatment caused an increased incidence of malrotated limbs, reduction in foetal and placental weights, reduced foetal viability and abortions at maternally toxic doses. The safety margin was 1.1 x the maximum recommended dose for faecal impaction in a 60 kg adult for malrotated limb and 2.9 x below the maximum recommended dose for the remaining findings.

Rabbits are sensitive animal test species to the effects of GI acting substances and the studies were conducted under exaggerated conditions with administered high dose volumes. The relevance of these findings to humans is unknown.

There are no long-term animal toxicity or carcinogenicity studies involving macrogol 3350, although there are toxicity studies using high levels of orally administered high molecular weight macrogols that provide evidence of safety at the recommended therapeutic dose.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

None

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

The shelf-life expiry date of this product shall be the date shown on the sachet and outer package of the product on the market in the country of origin.

Reconstituted solution: 24 hours

### **6.4 Special precautions for storage**

Sachet: Do not store above 25°C.

Reconstituted solution: Store in a refrigerator (2°C - 8°C) and covered.

### **6.5 Nature and contents of container**

Sachet: laminate consisting of four layers: low density polyethylene (LDPE), aluminium, LDPE and paper.

Pack size: boxes of 30 sachets.

### **6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

Any unused solution should be discarded within 24 hours.

**7 PARALLEL PRODUCT AUTHORISATION HOLDER**

B&S Healthcare  
Unit 4, Bradfield Road  
Ruislip  
Middlesex  
HA4 0NU  
United Kingdom

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1328/27/2

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 28th June 2012

**10 DATE OF REVISION OF THE TEXT**