SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Movicol Junior Choklad 6.9g sachet, powder for oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet of Movicol Junior Choklad contains the following active substances:

Macrogol 3350	6.563 g
Sodium Chloride	0.1754 g
Sodium Hydrogen Carbonate	0.0893 g
Potassium Chloride	0.0159 g

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

Sodium	65 mmol/l
Chloride	51 mmol/l
Potassium	5.4 mmol/l
Bicarbonate	17 mmol/l

Excipient(s) with known effect

Movicol Junior Choklad contains benzyl alcohol 7.0 mg per sachet.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution.

Free flowing white to light brown 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

Posology

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 to 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 for a prolonged period (at least 6-12 months). However safety and efficacy of Movicol Junior Choklad 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 Junior Choklad is for up to 7 days as follows:

Daily dosage regimen:

Number of Movicol Junior Choklad sachets							
Age (years)	**Day 1**	**Day 2**	**Day 3**	**Day 4**	**Day 5**	**Day 6**	**Day 7**
5-11	**4**	**6**	**8**	**10**	**12**	**12**	**12**

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 Junior Choklad 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 Junior Choklad 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 Junior Choklad is not recommended for treating faecal impaction in children with impaired renal function (see section 4.4 for warning about excipients.

Method of administration

Each sachet should be dissolved in 62.5mL (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 to 750mL 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 or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

The fluid content of Movicol Junior Choklad when re-constituted with water does not replace regular fluid intake and adequate fluid intake must be maintained.

Diagnosis of faecal impaction/faecal loading of the rectum should be confirmed by 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 Junior Choklad 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 Junior Choklad 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 Junior Choklad (see section 4.5).

Movicol Junior Choklad contains 7.0 mg benzyl alcohol per sachet. Benzyl alcohol may cause anaphylactoid reactions.

High volumes of benzyl alcohol should be used with caution and only if necessary, especially in subjects with kidney or liver impairment because of the risk of accumulation and toxicity (metabolic acidosis) of benzyl alcohol.

If used for more than a week in children less than 3 years old, medical advice should be provided due to increased risk of accumulation of benzyl alcohol.

Movicol Junior Choklad contains 93.4 mg (4.062 mmol) sodium (main component of cooking/table salt) per sachet. This is equivalent to 4.6% of the recommended maximum daily dietary intake of sodium for an adult.

In patients with swallowing problems, who need the addition of a thickener to solutions to enhance an appropriate intake, interactions should be considered, 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 Junior Choklad (see section 4.4).There have been isolated reports of decreased efficacy with some concomitantly administered medicinal products, e.g.

anti-epileptics. Therefore, other medicines should not be taken orally for one hour before, during and for one hour after taking Movicol Junior Choklad.

Movicol Junior Choklad may result in a potential interactive effect if used with starch-based food thickeners. 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

Pregnancy

There are limited amount of data from the use of Movicol in pregnant women. Studies in animals have shown indirect reproductive toxicity (see section 5.3). Clinically, no effects during pregnancy are anticipated, since systemic exposure to macrogol 3350 is negligible.

Movicol can be used during pregnancy.

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.

Fertility

There are no data on the effects of Movicol on fertility in humans. There were no effects on fertility in studies in male and female rats (see section 5.3).

4.7 Effects on ability to drive and use machines

Movicol Junior Choklad has no influence on the ability to drive and use machines.

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 Choklad.

In the treatment of chronic constipation, diarrhoea or loose stools normally respond to a reduction in dose.

Diarrhoea, abdominal distension, anorectal discomfort and mild vomiting are more often observed during the treatment for faecal impaction. Vomiting may be resolved if the dose is reduced or delayed.

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, <1/1000); and very rare (<1/10,000); not known (cannot be estimated from the available data).

System Organ Class	**Frequency**	***Adverse event***

Immune system disorders	Rare	Allergic reactions including anaphylactic reaction
	Not known	Dyspnoea, and skin reactions (see below)
Skin and subcutaneous tissue disorders	Not Known	Allergic skin reactions including angioedema, urticaria, pruritus, rash, erythema.
Metabolism and nutrition disorders	Not known	Electrolyte disturbances, particularly hyperkalaemia and hypokalaemia.
Nervous system disorders	Not known	Headache.
Gastrointestinal disorders	Very common	Abdominal pain, borborygmi.
	Common	Diarrhoea, vomiting, nausea and anorectal discomfort.
	Uncommon	Abdominal distension, flatulence.
	Not known	Dyspepsia and peri-anal inflammation.
General disorders and administration site conditions	Not known	Peripheral oedema.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation 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 via the national reporting system listed in Appendix V*.

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 defecation 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 gastro-intestinal 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.

There were no direct embryotoxic or teratogenic effects in rats even at maternally toxic levels that are a multiple of 66 x the maximum recommended dose in humans for chronic constipation and 25 x for faecal impaction. Indirect embryofetal effects, including reduction in fetal and placental weights, reduced fetal viability, increased limb and paw hyperflexion and abortions, were noted in the rabbit at a maternally toxic dose that was 3.3 x the maximum recommended dose in humans for treatment of chronic constipation and 1.3 x for faecal impaction. Rabbits are a sensitive animal test species to the effects of GI-acting substances and the studies were conducted under exaggerated conditions with high dose volumes administered, which are not clinically relevant. The findings may have been a consequence of an indirect effect of Movicol related to poor maternal condition as the result of an exaggerated pharmacodynamic response in the rabbit. There was no indication of a teratogenic effect.

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

Acesulfame potassium (E950)
Chocolate flavour*
(*Chocolate flavour contains maltodextrin (potato), gum arabic/acacia gum E414, vegetable oils and fats (coconut), propylene glycol E1520 and benzyl alcohol E1519)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

Reconstituted solution: 24 hours.

6.4 Special precautions for storage

Sachet: This medicinal product does not require any special storage conditions.
Reconstituted solution: Store in a refrigerator (2°C – 8°C) and covered.

6.5 Nature and contents of container

This product is available in rectangular sachet and tubular (stick-pack) sachet

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

Pack sizes: boxes of 6, 8, 10, 20, 30, 40, 50, 60 or 100 sachets.

Not all sachets and pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused solution should be discarded within 24 hours.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

[To be completed nationally]

8 MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed nationally]

10 DATE OF REVISION OF THE TEXT

2023-04-06