Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Wecol Paediatric 6.9 g powder for oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One sachet of Wecol Paediatric contains the following active ingredients:
Macrogol 3350, 6.563 g
Sodium chloride, 0.1754 g
Sodium hydrogen carbonate, 0.0893 g
Potassium chloride, 0.0233 g

Content of electrolyte ions when one sachet is dissolved in 62.5 mL water:
Sodium 65 mmol/l
Chloride 53 mmol/l
Bicarbonate 17 mmol/l
Potassium 5.0 mmol/l

Excipients with known effect
Each sachet contains:

- 12.22 mg potassium
- 93.86 mg sodium
- 0.38 mg sorbitol (E420)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution.

Free flowing white powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of chronic constipation in children aged 2 to 11 years.
For the treatment of faecal impaction in children aged 5 years or above. Faecal impaction is defined as refractory constipation with faecal loading in the rectum and/or colon.

4.2 Posology and method of administration

Posology

Chronic constipation
Children aged 2 to 6 years: starting dose of 1 sachet daily.
Children aged 7 to 11 years: starting dose of 2 sachets daily.

Adjust dose as required to produce regular, soft stools. Introduce dose increases every other day. Normal maximum dose is 4 sachets daily.

Doses may be reduced or temporarily omitted in cases of loose stools.

Treatment of children with chronic constipation needs to be for a prolonged period (at least 6 - 12 months). However, safety and efficacy of Wecol Paediatric has only been proved for a period of up to 3 months. Treatment should be stopped gradually and resume if constipation recurs.

Faecal impaction
A course of treatment with Wecol Paediatric takes up to 7 days, as follows:

Daily dose regimen

Number of Wecol Paediatric sachets							
Age	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
5 – 11 years	4	6	8	10	12	12	12

Take the daily number of sachets as divided doses over a 12 hour period. Stop treatment once disimpaction has occurred. Passage of a large volume of stools indicates disimpaction.

After disimpaction, it is recommended that the child follows an appropriate bowel management program to prevent reimpaction (dosage for prevention of recurrence follows dosage for chronic constipation; see above).

Wecol Paediatric is not recommended for children below 5 years of age for the treatment of faecal impaction, or in children under 2 years of age for the treatment of chronic constipation. For patients of 12 years of age and above, it is recommended to use Wecol.

Patients with imapired cardiovascular fuction
There are no clinical data in this group of patients. Use of Wecol Paediatric for the treatment of faecal impaction is not recommended in children with impaired cardiovascular function.

Patients with renal impairment
There are no clinical data in this group of patients. Use of Wecol Paediatric for the treatment of faecal impaction is not recommended in children with renal insufficiency.

Method of administration
The contents of 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 bowel diseases such as Crohn's disease, 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 Wecol Paediatric when re-constituted with water does not replace regular fluid intake and adequate fluid intake must be maintained.

Confirm diagnosis of faecal impaction / faecal loading of the rectum by physical or radiological examination of the abdomen and rectum.

Rarely in adults taking macrogol there have been reports of symptoms indicating a shift of fluid and electrolyte balance, e.g. oedema, shortness of breath, increasing fatigue, dehydration and cardiac failure. If these symptoms occur, stop treatment with Wecol Paediatric immediately. Measure electrolytes and treat any abnormality with appropriate counter measures.

When using high doses of this medicine to treat faecal impaction, use caution in patients with impaired gag reflex, reflux oesophagitis or reduced levels of consciousness.

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.

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

This medicine contains 0.31 mmol (12.22 mg) potassium per sachet. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

This medicinal product contains 93.86 mg sodium per sachet, equivalent to 4.69% of the WHO recommended maximum daily intake of 2 g sodium for an adult. May need to be taken into consideration by patients on a sodium controlled diet.

This medicine contains 0.38 mg sorbitol (E420) in each sachet.

4.5 Interaction with other medicinal products and other forms of interaction

Medicines in solid-dose form that are taken within one hour of administration of Wecol Paediatric may be flushed from the gastro-intestinal tract and not absorbed.

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

Absorption of other medicines could be transiently reduced due to an increased rate of gastro-intestinal transit induced by Wecol Paediatric (see section 4.4). There have been isolated reports of decreased efficacy with some concomitantly administered medicines, e.g. anti-epileptics. Therefore, other medicines should not be taken orally for one hour before, during and for one hour after taking Wecol Paediatric.

Wecol Paediatric may result in a potential interactive effect when used with starch-based food thickeners. The 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 Wecol Paediatric 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.

Wecol Paediatric 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.

Wecol Paediatric can be used during breastfeeding.

Fertility
There are no data on the effects of Wecol Paediatric 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

Wecol Paediatric 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 Wecol Paediatric.
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 reaction (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 HPRA Pharmacovigilance, Website: http://www.hpra.ie.

4.9 Overdose

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

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 macrogol 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 macrogol and lactulose as maintenance therapy after disimpaction, weekly stool frequency at the last visit was 9.4 (SD 4.46) in the macrogol group compared with 5.9 (SD 4.29). In the lactulose group 7 children re-impacted (23%) compared with no children in the macrogol 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, macrogol (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 macrogol paediatric required was 47.2.

5.2 Pharmacokinetic properties

Macrogol 3350 passes through the intestine unchanged. 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.

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 macrogol 3350 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

Colloidal Anhydrous Silica
Saccharin sodium
Orange flavour
Lemon Lime flavour
The lemon lime flavour contains:
Sorbitol (E420)
Alpha-tocopherol (E307)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened sachet: 3 years

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: four-layer laminate film consisting of ionomer coex, aluminum, polyethylene and paper.

Pack sizes: Packs of 30, 40, 50, 60 or 100 sachets.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

The contents of each sachet should be dissolved in 62.5 ml (quarter of a glass) of water. The solution should appear nearly colourless, slightly opalescent and without visible particles.

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.

Discard any unused solution within 24 hours.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA23138/001/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

May 2023