Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Wecol 6.9 g powder for oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One sachet of Wecol 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
Hydrogen carbonate 17 mmol/l
Potassium 5.0 mmol/l

Excipients with known effect
Each sachet contains:

- 12.22 mg (0.31 mmol) 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 adults, adolescents and the elderly.
For resolving faecal impaction in adults, adolescents and the elderly. Faecal impaction is defined as refractory constipation with faecal loading in the rectum and/or colon confirmed by physical or radiological examination of the abdomen and rectum.

4.2 Posology and method of administration

Posology

Chronic constipation
A course of treatment for constipation does not normally exceed two weeks, although this can be repeated if required.

As for all laxatives. Prolonged use is not usually recommended. Extended use may be necessary in the care of patients with severe chronic or resistant constipation, secondary to multiple sclerosis or Parkinson's disease, or induced by regular constipating medication, in particular opioids and antimuscarinics.

Adults, Adolescents and the Elderly
2-6 sachets daily in divided doses, accrding to individual response.

For extended use, dose can be adjusted down to 2-4 sachets daily.

Children (below 12 years old)
Not recommended. Alternative products are available for children.

Faecal impaction
Adults, Adolescents and the Elderly

A course of treatment for faecal impaction does not normally exceed 3 days.

Dosage is 16 sachets daily, all of which should be consumed within a 6-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 patient follows an appropriate bowel management programme to prevent reimpaction.

Children (below 12 years of age)
Not recommended. Alternative products are available for children.

Patients with impaired cardiovascular function
For the treatment of faecal impaction, the dose should be divided so that no more than four sachets are taken in any one hour.

Patients with renal insufficiency
No dosage change is necessary for the treatment of either constipation or faecal impaction.

Method of administration
The contents of each sachet should be dissolved in 62.5 ml (quarter of a glass) of water. For use in faecal impaction the correct number of sachets can be reconstituted in advance and kept covered and refrigerated for up to 6 hours. For example, dissolved 16 sachets in one litre of water for the treatment of faecal impaction.

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 Wecolwhen 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 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 (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.

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

4.5 Interaction with other medicinal products and other forms of interaction

Absorption of other medicines could be transiently reduced due to an increased rate of gastro-intestinal transit induced by Wecol (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.

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

Wecol 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

There are limited amount of data from the use of Wecol 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 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 can be used during breastfeeding.

Fertility
There are no data on the effects of Wecol 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 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 Compound Macrogol Oral Powder Sugar Free. Mild diarrhoea usually responds to dose reduction.

The frequency of the adverse effects is not known as it cannot be estimated from the available data.

System Organ Class	**Adverse Event**
Immune system disorders	Allergic reactions, including anaphylactic reactions, dyspnoea and skin reactions (see below).
Skin and subcutaneous tissue disorders	Allergic skin reactions including angioedema, urticaria, pruritus, rash,

	erythema.
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, anal discomfort.
General disorders and administration site conditions	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.

For the indication of faecal impaction controlled comparative studies have not been performed with other treatments (e.g. enemas). In a non-comparative study in 27 adult patients, macrogol 3350 13.8g cleared the faecal impaction in 12/27 (44%) after 1 day's treatment; 23/27 (85%) after 2 days' treatment and 24/27 (89%) at the end of 3 days.

Clinical studies in the use of macrogol 3350 in chronic constipation have shown that the dose needed to produce normal formed stools tends to reduce over time. Many patients respond to between 2-4 sachets of Wecol per day, but this dose should be adjusted depending on individual response.

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 embryofoetal effects, including reduction in foetal and placental weights, reduced foetal 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: Discard any solution not used within 6 hours.

6.4 Special precautions for storage

Sachet: Do not store above 25°C.

Reconstituted Solution: Store at 2 - 8°C (refrigerated 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.

For use in faecal impaction the correct number of sachets can be reconstituted in advance and kept covered and refrigerated for up to 6 hours. For example, dissolved 16 sachets in one litre of water for the treatment of faecal impaction.

Discard any solution not used within 6 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

PA23138/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

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