SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Macrolyte 13.8g sachet, powder for oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet of Macrolyte contains the following active substances:

Macrogol 3350 (Polyethylene Glycol) 3350 13.125 g

Sodium chloride 350.7 mg

Sodium bicarbonate178.5mg

Potassium chloride 46.6 mg

The content of electrolyte ions per sachet when made up to 125 ml of solution is as follows:

Sodium 65 mmol/l

Chloride 53 mmol/l

Potassium 5.4 mmol/l

Bicarbonate 17 mmol/l

Excipient(s) with known effect
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. Macrolyte is also effective in resolving faecal impaction, defined as refractory constipation with faecal loading of the rectum and/or colon.

4.2 Posology and method of administration

Posology

Chronic constipation

A course of treatment for constipation with Macrolyte does not normally exceed 2 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 older people: 1 –3 sachets daily in divided doses, according to individual response.

For extended use, the dose can be adjusted down to 1 or 2 sachets daily.

Children below 12 years old: Not recommended.

Faecal impaction

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

Adults, adolescents and older people: 8 sachets daily, all of which should be consumed within a 6 hour period.

Children below 12 years old: Not recommended.

Patients with impaired cardiovascular function: For the treatment of faecal impaction the dose should be divided so that no more than 2 sachets are taken in any one hour.

Patients with renal insufficiency: No dosage change is necessary for the treatment of constipation or faecal impaction (see section 4.4 for warning about excipients).

Method of administration

Each sachet should be dissolved in 125 ml water. For use in faecal impaction 8 sachets may be dissolved in 1 litre 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 Macrolyte when re-constituted with water does not replace regular fluid intake and adequate fluid intake must be maintained.

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

Mild adverse drug reactions are possible as indicated in Section 4.8. If patients develop any symptoms indicating shifts of fluids/electrolytes (e.g. oedema, shortness of breath, increasing fatigue, dehydration, cardiac failure) Macrolyte should be stopped immediately and electrolytes measured and any abnormality should be treated appropriately.

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

This medicinal product contains 186.87 mg (8.125 mmol) sodium per dose, equivalent to 9.3% of the WHO recommended maximum daily intake for sodium. The maximum daily dose of this product when used long term for constipation is equivalent to 28% of the WHO recommended maximum daily intake for sodium. Macrolyte is considered high in sodium. This should be particularly taken into account for those on a low salt diet.

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

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 Macrolyte (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 Macrolyte.

Macrolyte may result in a potential interactive effect if 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 Macrolyte 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.

Macrolyte 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.

Macrolyte can be used during breast-feeding.

Fertility

There are no data on the effects of Macrolyte 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

There is no effect on the ability to drive and use machines.

4.8 Undesirable effects

Reactions related to the gastrointestinal tract occur the 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 Macrolyte. 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, urticarial, pruritus, rash, erythema
Metabolism and nutrition disorders	Electrolyte disturbances, particularly hyperkalaemia and hypokalaemia
Nervous system	Headache
Gastrointestinal disorders	Abdominal pain, diarrhoea, vomiting, nausea, dyspepsia, abdominal distension, borborygmi, flatulence and anorectal 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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

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

Phamacotherapeutic 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, Macrolyte 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 Macrolyte in chronic constipation have shown that the dose needed to produce normal formed stools tends to reduce over time. Many patients respond to between 1 and 2 sachets a day, but this dose should be adjusted depending on individual response.

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 Macrolyte 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)

Lime and lemon flavour*

(*Lemon and lime flavour contains the following constituents: acacia solids, maltodextrin, lemon oil, lime oil, citral, citric acid and water.)

Macrolyte contains 186.87 mg (8.125 mmol) sodium (main component of cooking/table salt) per sachet. This is equivalent to 9.3% of the recommended maximum daily dietary intake of sodium for an adult.

6.2 Incompatibilities

None are known.

6.3 Shelf life

3 years.

Reconstituted solution: 6 hours.

6.4 Special precautions for storage

Sachet: Do not store above 25°C.

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

6.5 Nature and contents of container

Sachets: laminate consisting of four layers: low density polyethylene, aluminium, low density polyethylene and paper.

Pack sizes: boxes of 2, 6, 8, 10, 20, 30, 50, 60 or 100 sachets.

Not all pack sizes may be marketed

6.6 Special precautions for disposal

Any unused solution should be discarded 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(S)

PL 20011/0036

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21/02/2025

10 DATE OF REVISION OF THE TEXT

22/05/2025