SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

CosmoCol Plain powder for oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains the following quantitative composition of active ingredients:

Macrogol 3350	13.125 g
Sodium Chloride	0.3507 g
Sodium Hydrogen Carbonate	0.1785 g
Potassium Chloride	0.0466 g.

The content of electrolyte ions per sachet following reconstitution in 125 ml of water is equivalent to:

Sodium	65 mmol/l
Chloride	53 mmol/l
Hydrogen Carbonate (Bicarbonate)	17 mmol/l
Potassium	5 mmol/l

Excipients with known effect
Each sachet contains:
- 25 mg potassium
- 187 mg sodium

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution

Single-dose sachet containing a free flowing white powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of chronic constipation.

For resolving faecal impaction. 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 chronic constipation with CosmoCol Plain powder for oral solution 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 antimuscarincs.

Adults, adolescents and the elderly: 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. Alternative products are available for children.

Patients with renal insufficiency: No dosage change is necessary.

Faecal impaction
Adults, adolescents and the elderly: A course of treatment for faecal impaction does not normally exceed 3 days.
Dosage is 8 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 old: 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 two 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:
CosmoCol Plain powder for oral solution is for oral use.
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

CosmoCol Plain powder for oral solution is contraindicated in intestinal obstruction or perforation caused by functional or structural disorder of the gut wall, ileus and in patients with severe inflammatory conditions of the intestinal tract (e.g. ulcerative colitis, Crohn's disease and toxic megacolon).

Hypersensitivity to the active substances or any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

The fluid content of CosmoCol Plain powder for oral solution when reconstituted 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.
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) CosmoCol Plain powder for oral solution 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 gastrointestinal transit rate induced by CosmoCol Plain powder for oral solution (see section 4.5).

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.

This medicine contains 0.63 mmol (25 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 187 mg sodium per sachet, equivalent to 9.35% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

When used to treat chronic constipation, the maximum daily dose of this product is equivalent to 28.05% of the WHO recommended maximum daily intake for sodium.

CosmoCol Plain is considered high in sodium. This should be particularly taken into account for those on a low salt diet.

4.5 Interaction with other medicinal products and other forms of interaction

Macrogol 3350 raises the solubility of medicinal products that are soluble in alcohol and relatively insoluble in water. It is a theoretical possibility that absorption of these drugs could be reduced transiently during use with CosmoCol Plain powder for oral solution (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 CosmoCol Plain powder for oral solution.

CosmoCol Plain powder for oral solution 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 CosmoCol Plain powder for oral solution 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.
CosmoCol Plain powder for oral solution 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.
CosmoCol Plain powder for oral solution can be used during breast-feeding.

Fertility
There are no data on the effects of CosmoCol Plain powder for oral solution 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

CosmoCol Plain powder for oral solution 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 CosmoCol Plain powder for oral solution.
In the treatment of chronic constipation, diarrhoea or loose stools normally respond to a reduction in dose.
Diarrhoea, abdominal distension, anal 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 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 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Severe distension or pain can be treated using nasogastric aspiration. Vomiting or diarrhoea may induce extensive fluid loss, possibly leading to electrolyte disturbances that should be treated appropriately.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Osmotically acting laxatives, ATC code: A06A D65

Macrogol 3350 induces a laxative effect through its osmotic action in the gut. It 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 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 using the listed active substances for the treatment of chronic constipation have shown that the dose required to produce normally formed stools tends to decrease over time. Many patients, respond to between one and two sachets a day, but this dose should be adjusted depending on individual response.

5.2 Pharmacokinetic properties

Macrogol 3350 is virtually unabsorbed from the gastro-intestinal tract and is excreted, unaltered, in faeces. 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 or 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

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

Reconstituted solution: 24 hours

6.4 Special precautions for storage

Sachet: Do not store above 25 °C.

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

6.5 Nature and contents of container

The sachet is composed of paper, ethylene / methacrylic acid co-polymer and aluminium.

Sachets are packed in cartons of 20, 30, 50, 60 (2x30) and 100 (2x50).

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

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

7 MARKETING AUTHORISATION HOLDER

Stirling Anglian Pharmaceuticals Ltd

Hillington Park Innovation Centre

1 Ainslie Road

Hillington Park

Glasgow

G52 4RU

United Kingdom

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