

CosmoCol[®] powder for oral solution – Abbreviated Prescribing Information

Please refer to the appropriate Summary of Product Characteristics (SmPC) before prescribing CosmoCol[®] powder for oral solution.

CosmoCol Orange, Lemon and Lime Flavour, Orange Flavour, Lemon and Lime Flavour and CosmoCol Plain. Each sachet of powder contains 13.125 g macrogol 3350, 0.3507 g sodium chloride, 0.1785 g sodium hydrogen carbonate and 0.0466 g potassium chloride as active ingredients. **CosmoCol Paediatric and CosmoCol Half 6.9 g powder.** Each sachet of powder contains 6.563 g macrogol 3350, 0.1754 g sodium chloride, 0.0893 g sodium hydrogen carbonate and 0.0233 g potassium chloride as active ingredients. Products may contain orange, lemon and lime flavourings as labelled. **Indications:** The treatment of chronic constipation in adults, the elderly and children aged at least 2 years. The treatment of faecal impaction in patients aged 5 years or above. **Dosage and administration:**

Chronic constipation: Adults and adolescents aged 12 years and above:

CosmoCol: 1–3 sachets daily in divided doses, according to individual response.

Each sachet should be dissolved in 125 ml of water. **CosmoCol Half:** 2–6 sachets daily according to individual response. Each sachet should be dissolved in 62.5 ml

(quarter of a glass) of water. **CosmoCol Paediatric for children aged 2 – 11 years:**

1–4 sachets daily adjusted according to individual response. Each sachet should be dissolved in 62.5 ml (quarter of a glass) of water. **Faecal impaction: Adults and**

adolescents aged 12 years and above: CosmoCol: 8 sachets daily all of which should be consumed within a 6 hour period. A course of treatment does not normally exceed 3 days. This dosage regime should be stopped as soon as the impaction is cleared. **CosmoCol Half:** 16 sachets daily. **CosmoCol Paediatric for children aged 5–11 years:** A course of treatment may take up to 7 days. Take the daily number of sachets in divided doses over a 12 hour period. In adults with impaired cardiovascular function and faecal impaction the dose should be divided so that no more than 4 sachets are taken in any one hour.

Number of CosmoCol Paediatric sachets for the treatment of faecal impaction							
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

The use of CosmoCol Paediatric to treat faecal impaction is not recommended in children with impaired cardiovascular or renal function.

Contraindications: CosmoCol 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.

Warnings and precautions: If patients develop any symptoms indicating shifts of fluids/electrolytes (e.g. oedema, shortness of breath, increasing fatigue, dehydration, cardiac failure) CosmoCol should be stopped immediately and electrolytes measured and any abnormality should be treated appropriately. 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. The lemon and lime flavour in CosmoCol Orange, Lemon and Lime Flavour sachets, Lemon and Lime Flavour sachets, The paediatric product may counteract

the thickening effect of starch. Paediatric and Half products contains sorbitol (E420). Patients with rare hereditary problems of fructose intolerance should not take this medicine.

Interactions: 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. There have been isolated reports of decreased efficacy with some concomitantly administered medicinal products, e.g. anti-epileptics. Other medicines should not be taken orally for one hour before, during and for one hour after taking CosmoCol. **Pregnancy and lactation:** There is no experience with the use of CosmoCol during pregnancy and lactation and it should only be used if considered essential by the physician. No effects during pregnancy or breastfeeding are anticipated as systemic exposure to macrogol 3350 is negligible. **Effects on ability to drive and use machines:** CosmoCol has no influence on the ability to drive and use machines. **Undesirable effects:** The following adverse events have been reported at an unknown frequency. Allergic reactions including anaphylaxis, angioedema, dyspnoea, rash, erythema, urticaria and pruritus. Electrolyte disturbance particularly hyperkalaemia and hypokalaemia. Headache. Gastrointestinal disorders including diarrhoea, vomiting, nausea, dyspepsia, abdominal distension, borborygmi, flatulence and discomfort. Peripheral oedema. **Overdose:** Refer to the SmPC.

Legal category: P (CosmoCol Paediatric: POM)

Pack sizes:

CosmoCol Orange, Lemon and Lime	
Flavour:	30 sachets NHS price: £6.60
CosmoCol Orange Flavour:	20 sachets NHS price: £4.60
	30 sachets NHS price: £6.60
CosmoCol Lemon and Lime Flavour:	20 sachets NHS price: £4.60
	30 sachets NHS price: £6.60
CosmoCol Plain: (unflavoured)	30 sachets NHS price: £6.60
CosmoCol Half: (orange, lemon & lime)	30 sachets NHS price: £5.20
CosmoCol Paediatric: (orange, lemon & lime)	30 sachets NHS price: £4.32

Marketing Authorisation Holder:

Stirling Anglian Pharmaceuticals Ltd,
Hillington Park Innovation Centre,
1 Ainslie Road,
Hillington Park,
Glasgow G52 4RU

Marketing Authorisation Number(s):

PL 42582/0001 – 0003, 42582/0007 – 0008, 42582/0010

Further information is available at medinfo@stirlinganglianpharmaceuticals.com
or via the office number **0330 1359 499**

Date of preparation: 22 June 2026

Unique Code: 26-API-001 v3.0

Adverse events should be reported. Reporting forms and information can be found at <http://yellowcard.mhra.gov.uk> or downloaded from Google Play or the Apple App store. Adverse events should also be reported to **Stirling Anglian Pharmaceuticals** on **0330 1359 499** or by emailing **medinfo@stirlinganglianpharmaceuticals.com**