

CosmoCol Paediatric

6.9 g, powder for oral solution

Macrogol 3350, sodium chloride, sodium hydrogen carbonate, potassium chloride

Read all of this leaflet carefully before you give this medicine to your child because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for your child. Do not pass it on to others. It may harm them, even if their symptoms are the same as your child's.
- If you or your child notice any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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2. What you need to know before you give CosmoCol Paediatric
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1. What CosmoCol Paediatric is and what it is used for

CosmoCol Paediatric is a laxative.

This medicine is used to treat:

- chronic constipation in children aged 2–11 years.
- impaction in children from 5 years. Impaction is persistent constipation, where a large volume of stools cause a blockage of the rectum and/or colon.

A medicine with a higher dose is recommended for children over the age of 12.

2. What you need to know before you give CosmoCol Paediatric

Do not give CosmoCol Paediatric to your child if your doctor has told you that your child:

- is allergic to Macrogol 3350, sodium chloride, sodium hydrogen carbonate, potassium chloride or any of the other ingredients in this medicine (listed in section 6).
- has a blockage in their intestine.
- has a perforated gut wall.
- has a severe inflammatory bowel disease like ulcerative colitis, Crohn's disease or toxic megacolon.

Warnings and precautions

Talk to your doctor or pharmacist before giving CosmoCol Paediatric to your child if your child has heart or kidney problems, an impaired gag reflex, difficulty swallowing or suffers from heartburn.

When taking CosmoCol Paediatric your child should continue to take plenty of fluids. The fluid content of CosmoCol Paediatric should not replace your child's regular liquid intake.

Other medicines and CosmoCol Paediatric

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines.

Some medicines, such as medicines for epilepsy, may be less effective during use of CosmoCol Paediatric.

When taking large volumes of CosmoCol Paediatric (e.g. for faecal impaction), other medicines may be flushed through the digestive system. Your child should not take any other medicines by mouth together with CosmoCol Paediatric and for one hour before and for one hour after taking CosmoCol Paediatric.

If you need to thicken fluids in order for your child to swallow them safely, CosmoCol Paediatric may counteract the effect of the thickener.

Giving CosmoCol Paediatric with food and drink

This medicine can be given at any time with or without food or drink.

Pregnancy and breast-feeding

CosmoCol Paediatric can be used during pregnancy and breastfeeding.

Ask your pharmacist or doctor for advice before giving CosmoCol Paediatric.

CosmoCol Paediatric contains potassium

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.

CosmoCol Paediatric contains sodium

This medicine contains 93.86 mg sodium (main component of cooking/table salt) in each sachet. This is equivalent to 4.69% of the recommended maximum daily dietary intake of sodium for an adult. May need to be taken into consideration by patients on a sodium controlled diet.

CosmoCol Paediatric contains sorbitol (E420)

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

3. How to use CosmoCol Paediatric

Always give this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Chronic Constipation:

The recommended dose depends on your child's age and their response to treatment.

- For children aged 2 to 6 years, start with a dose of 1 sachet each day.
- For children aged 7 to 11 years, start with a dose of 2 sachets each day.

Your doctor may tell you to increase the number of sachets taken until your child has a soft bowel movement. If the dose needs increasing, do this every other day. Normally, no more than 4 sachets are needed each day.

Your child does not need to drink the whole dose at once. If your child prefers, half the dose can be drunk in the morning and half in the evening.

Faecal impaction:

Before your child takes CosmoCol Paediatric for faecal impaction, your doctor must check to confirm that your child has this condition.

The recommended dose is:

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

On each day, doses can be spread out over 12 hours (e.g. 8am–8pm). You will know the medicine has worked when your child passes large volumes of stools and/or watery diarrhoea. Once the medicine has worked, treatment can be stopped.

To prevent further problems from faecal impaction, your doctor may advise that you continue to give this medicine to your child. You should give the dose for treating chronic constipation.

How to mix

- Tear open the sachet and pour the contents into a glass.
- Add about 62.5 ml or a quarter of a glass of water to the glass.
- Stir well until all the powder has dissolved and the solution is clear or slightly hazy, then give it to your child to drink.
- If your child is taking CosmoCol Paediatric for faecal impaction it may be easier to dissolve 12 sachets in 750 ml of water.

Duration of treatment

Chronic constipation:

Treatment needs to be for a prolonged period of time, at least 6–12 months.

Faecal impaction:

Treatment can be for up to 7 days.

If your child takes more CosmoCol Paediatric than they should

Your child may develop excessive diarrhoea. If this occurs, stop your child taking CosmoCol Paediatric and make sure they drink plenty of fluids. If you are worried contact your doctor or pharmacist.

If you forget to give CosmoCol Paediatric

Give the dose as soon as you remember. Do not give a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop giving CosmoCol Paediatric and tell your doctor immediately if your child has:

- a serious allergic reaction which causes difficulty in breathing, breathlessness or swelling of the face, lips, tongue or throat.
- signs of a change in their body's fluid or electrolyte levels (salts levels such as high and low levels of potassium in the blood) such as swelling (mainly in the ankles), shortness of breath, feeling weak, increasingly tired or increased thirst with headache.

Other side effects include:

Very common side effects (may affect more than 1 in 10 people)

- stomach pains
- rumbling stomach

Common side effects (may affect up to 1 in 10 people):

- diarrhoea
- feeling sick or being sick
- pain or discomfort around the bottom

If your child is being treated for **chronic constipation**, diarrhoea will usually improve when the dose is reduced.

Uncommon side effects (may affect up to 1 in 100 people)

- feeling bloated
- wind

Not known (frequency cannot be estimated from the available data)

- allergic reactions which may cause a skin rash (hives), itching, reddening of the skin or a nettle rash
- indigestion, swollen hands, feet or ankles, headaches, high or low levels of potassium in the blood

Reporting of side effects

If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Malta	United Kingdom
ADR Report Website: www.medicinesauthority.gov.mt/adrportal	Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store CosmoCol Paediatric

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the sachet and carton. The expiry date refers to the last day of the month.

Do not store your CosmoCol Paediatric above 25°C.

Once you have made up CosmoCol Paediatric in water, if your child cannot drink it straight away, keep it covered and in the fridge (2–8°C). Throw away any solution not used within 24 hours.

Do not throw away any medicines via wastewater or household waste.

Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What CosmoCol Paediatric contains

One sachet of CosmoCol 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

When the sachet contents are dissolved in a quarter of a glass (62.5 ml) of water, each sachet gives the equivalent of:

Sodium	65 millimoles/litre
Chloride	53 millimoles/litre
Hydrogen carbonate	17 millimoles/litre
Potassium	5.0 millimoles/litre

The other ingredients are colloidal anhydrous silica, saccharin sodium, orange flavour and lemon lime flavour. The flavourings contain sorbitol (E420) and alpha-tocopherol (E307).

This medicinal product contains potassium, sodium and sorbitol (E420). See section 2 'CosmoCol Paediatric contains potassium/sodium/sorbitol (E420)'.

What CosmoCol Paediatric looks like and contents of the pack

CosmoCol Paediatric is a white powder which comes in a sachet. CosmoCol Paediatric is available in boxes of 30, 40, 50, 60 or 100 sachets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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

Manufacturer

Klocke Pharma-Service GmbH
Strassburger Strasse 77
77767 Appenweiler
Germany

For any information about this medicine, please contact the Marketing Authorisation Holder.

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