

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

1. What CosmoCol Paediatric is and what it is used for
2. What you need to know before you give CosmoCol Paediatric
3. How to use 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.
- treat 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).
- your child has a blockage in their intestine.
- your child has a perforated gut wall.
- your child has a severe inflammatory bowel disease like ulcerative colitis, Crohn's disease or toxic megacolon.

Warnings and precautions

If your child has heart or kidney problems, an impaired gag reflex or suffers from heart-burn, talk to your doctor before giving CosmoCol Paediatric.

Other medicines and CosmoCol Paediatric

Some medicines, such as medicines for epilepsy, may be less effective during use of CosmoCol Paediatric. Tell your doctor about any other medicines that your child is taking.

Do not give your child other medicines within one hour of giving CosmoCol Paediatric.

If you need to thicken fluids in order 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.

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 give CosmoCol Paediatric

Always follow your doctor's instructions when giving this medicine to your child. 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.

Your child will need treatment over a long period of time, at least 6–12 months.

Faecal impaction:

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

A treatment course for faecal impaction lasts up to 7 days.

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 water until the glass is about a quarter full.
- Stir until all the powder has dissolved and the solution is clear or slightly hazy, then give it to your child to drink.

Duration of treatment

Chronic constipation:

Treatment needs to be for a prolonged period, 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.

4. Possible side effects

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

Tell your doctor immediately and stop giving CosmoCol Paediatric if your child has a serious allergic reaction which causes difficulty in breathing or swelling of the face, lips, tongue or throat.

Very common side effects (more than 1 person in 10)

- stomach pains
- rumbling stomach

Common side effects (more than 1 in 100 but less than 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 (more than 1 in 1000 but less than 1 in 100 people)

- feeling bloated
- wind

Rare side effects (less than 1 person in 1000)

- allergic reactions, which may include, breathlessness or difficulty in breathing.

Other side effects reported include:

Skin rash (hives), itching, reddening of the skin or a nettle rash, swollen hands, feet or ankles, headaches, indigestion, 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 quarter of a glass of water, each sachet gives the equivalent of:

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

The other ingredients are colloidal anhydrous silica, saccharin sodium, orange flavour, and lemon lime flavour. The flavorings 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. Boxes of 30, 40, 50, 60 or 100 sachets are available.

Marketing Authorisation Holder

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