

CosmoCol Half

6.9 g, powder for oral solution

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

Read all of this leaflet carefully before you take this medicine 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 you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you 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 Half is and what it is used for
2. What you need to know before you use CosmoCol Half
3. How to take CosmoCol Half
4. Possible side effects
5. How to store CosmoCol Half
6. Contents of the pack and other information

1. What CosmoCol Half is and what it is used for

CosmoCol Half is a laxative.

This medicine is used in adults, adolescents and elderly to treat:

- chronic constipation.
- impaction. Impaction is persistent constipation, where a large volume of stools cause a blockage of the rectum and/or colon.

It is not recommended for children below 12 years of age.

2. What you need to know before you use CosmoCol Half

Do not take CosmoCol Half if you:

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

Warnings and precautions

Talk to your doctor or pharmacist before taking CosmoCol Half if you have heart or kidney problems, an impaired gag reflex, difficulty swallowing or suffer from heartburn.

When taking CosmoCol Half you should continue to take plenty of fluids. The fluid content of CosmoCol Half should not replace your regular liquid intake.

Heart conditions

Follow the special instructions in section 3 if you are taking CosmoCol Half for faecal impaction.

Other medicines and CosmoCol Half

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

You should not take any other medicines by mouth together with CosmoCol Half and for one hour before and for one hour after taking CosmoCol Half.

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

Taking CosmoCol Half with food and drink

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

Pregnancy and breast-feeding

CosmoCol Half can be used during pregnancy and breastfeeding. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

CosmoCol Half does not affect your ability to drive or use machines.

CosmoCol Half 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 Half 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.

CosmoCol Half contains sorbitol (E420)

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

3. How to take CosmoCol Half

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Chronic Constipation:

The recommended dose is 2 to 6 sachets daily, taken in divided doses. You should not normally need to take this medicine for more than 3 days.

Faecal impaction:

Before you take CosmoCol Half for faecal impaction, your doctor must check to confirm that you have this condition. The recommended dose is 16 sachets daily, all of which should be consumed within 6 hours for up to 3 days if required. If you have a heart condition, do not take more than 4 sachets in any 1 hour.

To prevent further problems from faecal impaction, your doctor may advise that you continue taking this medicine. You should use 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, before drinking.

Duration of treatment

Chronic constipation:

Treatment usually lasts about 2 weeks. If you need to take CosmoCol Half for longer, please see your doctor. If your constipation is caused by an illness such as Parkinson's disease or multiple sclerosis (MS), or if you take medicines that cause constipation, your doctor may recommend that you take this medicine for longer than 2 weeks. If you need to take CosmoCol Half for longer, please see your doctor.

Usually for long-term treatment the dose can be lowered to either 2 or 4 sachets daily.

Faecal impaction:

Treatment can be for up to 3 days.

If you take more CosmoCol Half than you should

You may develop excessive diarrhoea. If this occurs, stop taking CosmoCol Half and drink plenty of fluids. If you are worried contact your doctor or pharmacist.

If you forget to take CosmoCol Half

Take the dose as soon as you remember. Do not take 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 taking CosmoCol Half and tell your doctor immediately if you have:

- a serious allergic reaction which causes difficulty in breathing, breathlessness or swelling of the face, lips, tongue or throat.
- signs of a change in your 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:

- Allergic reactions which may cause a skin rash, itching, reddening of the skin or a nettle rash, swollen hands, feet or ankles, headaches.
- Sometimes you may have indigestion, stomach ache or rumbles. You may also feel bloated, suffer from wind, feel sick or vomit, may also experience soreness of the anus (bottom) and mild diarrhoea.

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

Reporting of side effects

If you get 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/adportal	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 Half

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 Half above 25°C.

Once you have made up CosmoCol Half in water, if you cannot drink it straight away, keep it covered and in the fridge (2–8°C). Throw away any solution not used within 6 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 Half contains

One sachet of CosmoCol Half 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 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 flavourings contain sorbitol (E420) and alpha-tocopherol (E307).

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

What CosmoCol Half looks like and contents of the pack

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

Marketing Authorisation Holder

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

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