

Package leaflet: Information for the user

CosmoCol Orange Flavour

Powder for oral solution

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

This medicine is available without prescription. However, you still need to take CosmoCol Orange Flavour carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 14 days.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What CosmoCol Orange Flavour is and what it is used for
2. What you need to know before you take CosmoCol Orange Flavour
3. How to take CosmoCol Orange Flavour
4. Possible side effects
5. How to store CosmoCol Orange Flavour
6. Contents of the pack and other information

1. What CosmoCol Orange Flavour is and what it is used for

CosmoCol Orange Flavour is a laxative used for the treatment of long-term (chronic) constipation and faecal impaction (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. Macrogol 3350 makes your faeces softer and easier to pass, giving you relief from constipation. The electrolytes (salts) help to maintain your body's normal levels of sodium, potassium and water while you are being treated for constipation.

2. What you need to know before you take CosmoCol Orange Flavour

Do not take CosmoCol Orange Flavour if you:

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

If any of these apply to you, please talk to your doctor or pharmacist for further advice.

Warnings and precautions

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

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

Heart conditions

Follow the special instructions in section 3 if you have a heart condition and are taking CosmoCol Orange Flavour for faecal impaction.

Other medicines and CosmoCol Orange Flavour

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

Some medicines, e.g. anti-epileptics, may not work as effectively during use with CosmoCol Orange Flavour.

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

CosmoCol Orange Flavour with food and drink

CosmoCol Orange Flavour can be taken at any time with or without food or drink.

Pregnancy and breast-feeding

CosmoCol Orange Flavour can be taken during pregnancy and whilst breastfeeding. If you are pregnant, trying to become pregnant or breastfeeding, ask your pharmacist or doctor for advice before taking CosmoCol Orange Flavour.

Driving and using machines

CosmoCol Orange Flavour has no effect on the ability to drive or use machinery.

CosmoCol Orange Flavour contains potassium

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.

CosmoCol Orange Flavour contains sodium

This medicine contains 187 mg sodium (main component of cooking/table salt) in each sachet. This is equivalent to 9.35 % of the recommended maximum daily dietary intake of sodium for an adult.

When used to treat chronic constipation, the maximum recommended daily dose of this medicinal product contains 561 mg sodium (found in table salt). This is equivalent to 28.05 % of the adult recommended maximum daily dietary intake for sodium.

Talk to your pharmacist or doctor if you need CosmoCol Orange Flavour on a daily basis for a prolonged period of time, especially if you have been advised to have a low salt diet.

3. How to take CosmoCol Orange Flavour

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.

Treatment of chronic constipation in adults, children (aged 12 years and above) and the elderly:

The recommended dose for constipation is 1 sachet taken 1–3 times daily.

Duration of treatment

This course of treatment for constipation should not normally last longer than 2 weeks. If you need to take CosmoCol Orange Flavour 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 CosmoCol Orange Flavour for longer than 2 weeks. If you need to take CosmoCol Orange Flavour for longer, please see your doctor. Usually for long-term treatment the dose can be lowered to either 1 or 2 sachets a day.

Treatment of faecal impaction in adults, children (aged 12 years and above) and the elderly:

Before you take CosmoCol Orange Flavour for faecal impaction, your doctor must check to confirm that you have this condition. The recommended dose is 8 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 2 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.

Duration of treatment

The course of treatment for faecal impaction should be stopped when a large volume of stools is passed and does not normally last longer than 3 days.

How to mix

Open the sachet and pour the contents into a glass. Add about 125 ml (¼ pint) of water to the glass. Stir well until the powder has dissolved and then drink it. If you are taking CosmoCol Orange Flavour for faecal impaction it may be easier to dissolve 8 sachets in 1 litre of water.

If you take more CosmoCol Orange Flavour than you should

This can cause severe pain and swelling in your abdomen (stomach), or vomiting (sickness) or diarrhoea. If this happens, contact your doctor or pharmacist.

If you forget to take CosmoCol Orange Flavour

If you forget to take a dose, take it as soon as you remember and then continue on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking CosmoCol Orange Flavour

To get the most benefit from CosmoCol Orange Flavour, always finish the course of treatment according to the directions in this package leaflet. This will make sure that your constipation is cleared, otherwise the symptoms you are suffering from may persist.

You must contact a doctor if your symptoms worsen or do not improve after 14 days.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

Stop taking CosmoCol Orange Flavour and tell your doctor immediately if you have:

- **a serious allergic reaction which causes difficulty in breathing or swelling of the face, lips, tongue or throat.**
- **signs of a change in your body's fluid or electrolyte levels 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.
- 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 may have mild diarrhoea when starting to take CosmoCol Orange Flavour. These side effects generally get better if you reduce the amount of CosmoCol Orange Flavour you take.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store CosmoCol Orange Flavour

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 carton and sachet. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not use this medicine if you notice that any of the sachets are damaged.

Reconstituted CosmoCol Orange Flavour solution can be covered and stored in the refrigerator (2°C to 8°C), and should be used within 24 hours. After 24 hours, any unused solution should be discarded.

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 Orange Flavour contains

One sachet of CosmoCol Orange Flavour contains the following active ingredients:

Macrogol 3350	13.125 g
Sodium chloride	0.3507 g
Sodium hydrogen carbonate	0.1785 g
Potassium chloride	0.0466 g

When the sachet contents are dissolved in 125 ml (¼ pint) 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 and orange flavour (Orange flavour contains: flavouring substances and flavouring preparations, maltodextrin, acacia gum, alpha-tocopherol).

This medicinal product contains potassium and sodium. See section 2 'CosmoCol Orange Flavour contains potassium/sodium'.

What CosmoCol Orange Flavour looks like and contents of the pack

CosmoCol Orange Flavour is a white powder.

Each sachet contains 13.8 g of powder and is packed in cartons containing 20, 30, 50, 60 (2x30) and 100 (2x50) sachets. Not all pack sizes may be marketed.

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This leaflet was last revised in February 2023