

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 in CosmoCol Orange Flavour
- if you have a perforated gut (bowel) wall
- if you have a blockage in your intestine (gut obstruction, ileus)
- if you have severe inflammatory bowel disease such as ulcerative colitis, Crohn's disease or toxic megacolon

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

Other medicines and CosmoCol Orange Flavour

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

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription.

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

If you are pregnant or breast-feeding talk to your doctor before taking CosmoCol Orange Flavour.

Driving and using machines

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

Important information about some of the ingredients of CosmoCol Orange Flavour

CosmoCol Orange Flavour contains 0.63 mmol (25 mg) of potassium per sachet. This should be taken into consideration if you take more than one sachet daily and you have reduced kidney function, or if you are on a controlled potassium diet.

CosmoCol Orange Flavour contains 8.1 mmol (187 mg) of sodium per sachet. This should be taken into consideration if you are on a controlled sodium diet.

3. How to take CosmoCol Orange Flavour**Treatment of chronic constipation in adults, children (aged 12 years and above) and the elderly:**

The recommended dose for constipation is one sachet taken one to three times daily.

Duration of treatment

This course of treatment for constipation should not normally last longer than 2 weeks.

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.

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 or a quarter pint of water to the glass. Stir well until the powder has dissolved and then drink it.

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, CosmoCol Orange Flavour can cause side effects, although not everybody gets them.

If you experience any of the following side effects, stop taking CosmoCol Orange Flavour and see your doctor immediately:

- signs of an allergy, such as a rash, itching, shortness of breath or difficulty in breathing.
- signs of a change in your body's fluid or electrolyte levels (salts levels), such as swelling (mainly in the ankles), feeling weak, increasingly tired or increased thirst with headache

The following side effects are also possible:

- abdominal (stomach) pain
- mild diarrhoea (when starting to take CosmoCol Orange Flavour, this usually stops if you reduce the number of sachets you take)
- nausea (feeling sick)
- vomiting
- swelling of your abdomen (feeling bloated)
- stomach rumbling

- flatulence (wind)
- soreness of the anus (bottom)

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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

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 is 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

The active substances are:

Each sachet contains:

macrogol 3350	13.125 g
sodium chloride	0.3507 g
sodium hydrogen carbonate	0.1785 g
potassium chloride	0.0466 g

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).

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 2, 6, 8, 10, 20, 30, 50, 60 (2x30) and 100 (2x50) sachets.

Not all of these pack sizes are marketed.

Marketing Authorisation Holder

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