

Package leaflet: Information for the user

Omnicol powder for oral solution, sachet

macrogol 3350, sodium chloride, sodium bicarbonate, potassium chloride

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

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- If you have bought this medicine without a prescription you must talk to a doctor if you do not feel better or if you feel worse after 14 days.

What is in this leaflet

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

1. What Omnicol is and what it is used for

The name of this medicine is Omnicol. It is a laxative for the temporary treatment of constipation in adults, adolescents and elderly. It is not recommended for children below 12 years of age.

Omnicol helps you to have a comfortable bowel movement even if you have been constipated for a long time. When Omnicol is prescribed by a doctor, it can also be used for long term treatment and for the treatment of severe constipation called faecal impaction.

2. What you need to know before you take Omnicol

Do not take Omnicol

- if you are allergic to macrogol (polyethylene glycol), sodium chloride, sodium bicarbonate, potassium chloride or any of the other ingredients of this medicine (listed in section 6)
- if you have blockage in your intestine (gut obstruction, ileus)
- if you have a perforated gut wall
- if you have severe inflammatory bowel disease like ulcerative colitis, Crohn's disease or toxic megacolon

Warnings and precautions

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

Heart conditions

Follow the specific instructions in section 3 if you have heart problems and have been prescribed Omnicol by a doctor for very severe constipation, known as faecal impaction.

Other medicines and Omnicol

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

If you have swallowing problems and need food thickeners to thicken fluids in order to swallow them safely, avoid mixing Omnicol with starch-based food thickeners. Omnicol may counteract the effect of starch-based food thickeners causing preparations that need to remain thick for people with swallowing problems to become thin.

Pregnancy and breast-feeding

Omnicol can be taken during pregnancy and whilst breast-feeding.

Driving and using machines

Omnicol does not affect your ability to drive or use machines.

Omnicol contains sodium

This medicinal product contains 187 mg sodium (main component of cooking/table salt) per sachet. 3 sachets are equivalent to 28% of the recommended maximum daily intake for sodium for adults. Talk to your doctor or pharmacist if you need 3 or more sachets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

3. How to take Omnicol

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.

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

Dissolve the content of each sachet in 125 ml (1/2 glass) of water and drink.

Constipation:

A dose of Omnicol is 1 sachet dissolved in 125 ml (1/2 glass) of water. Take this 1–3 times a day according to the severity of your constipation. The doses are taken evenly throughout the day.

Faecal impaction:

Before you take Omnicol for faecal impaction, it should be confirmed that you have this condition.

A dose of 8 sachets a day of Omnicol is needed for the treatment of faecal impaction. Each sachet dissolved in 125 ml (1/2 glass) of water. The 8 sachets should be taken 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 one hour.

How to mix:

Open the sachet and pour the contents into a glass. Add about 125 ml or 1/2 glass of water. Stir well until all the powder has dissolved and the solution is clear or slightly opalescent, then drink it. If you are taking Omnicol for faecal impaction it may be easier to dissolve 8 sachets in 1 litre of water.

Duration of treatment:**Constipation:**

Treatment with Omnicol for temporary constipation usually lasts for about 2 weeks. You must talk to a doctor if you feel worse or if you do not feel better after 14 days. 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 Omnicol for longer than 2 weeks. If you need to take Omnicol for longer, please see your doctor. Usually for long term treatment the dose can be lowered to either 1 or 2 sachets a day.

Faecal impaction:

Treatment with Omnicol for faecal impaction can be for up to 3 days.

If you take more Omnicol than you should

Too much Omnicol can cause diarrhoea. Stop treatment with Omnicol until the diarrhoea subsides and then continue with a lower dose. Check with your doctor or pharmacist if you are not sure.

If you suffer from severe diarrhoea or vomiting you should contact a doctor as soon as possible as you may require treatment to prevent salt deficiency caused by fluid loss.

If you forget to take Omnicol

Take the dose as soon as you remember to take it.

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.

Tell your doctor immediately and stop taking Omnicol if you:

- Get a serious allergic reaction which causes difficulty in breathing, or swelling of the face, lips, tongue or throat.

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 and high and low levels of potassium in the blood.

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 Omnicol. These side effects generally get better if you reduce the amount Omnicol 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 national reporting system](#) listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Omnicol

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 sachets and carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Reconstituted solution should be stored well covered in a refrigerator (2°C-8°C) and is stable for 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 Omnicol contains

Each sachet of Omnicol contains the following active ingredients:

Macrogol 3350	13.125 g
Sodium Chloride	0.351 g
Sodium Bicarbonate	0.178 g
Potassium Chloride	0.047 g

When it is made into a drink with 125 millilitres of water, each sachet gives the equivalent of:

Sodium	65 millimoles/litre
Chloride	53 millimoles/litre
Potassium	5.4 millimoles/litre
Bicarbonate	17 millimoles/litre

The other ingredients are:

acesulfame potassium (E950), orange flavour (containing the following ingredients: orange oil, acacia solids (E414), maltodextrin, citral, limonene)

What Omnicol looks like and contents of the pack

Appearance: Omnicol is a free flowing off-white powder

Pack sizes: 2, 4, 6, 8, 10, 12, 14, 20, 22, 24, 30, 50, 60, 100, 200, or 250 sachets.

Not all pack sizes may be marketed.

[To be completed nationally]

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicine is authorised in the Member States of the European Economic Area under the following names:

<{Name of the Member State}> <{Name of the medicine}>
<{Name of the Member State}> <{Name of the medicine}>
< United Kingdom (Northern Ireland)> <{Name of the medicine}>

This leaflet was last revised in

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