

DulcoSoft®

ORAL SOLUTION
macrogol 4000



What you should know about DULCOSOFT®

Please read these instructions for use carefully because they include important information you have to consider before using this product. If you are unsure or if you have any further questions, ask your physician or pharmacist.

DULCOSOFT® is a medical device for the symptomatic treatment of constipation and the softening of hard stools.

Keep this leaflet. You may want to read it again.

In this leaflet:

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1. What is DULCOSOFT® and what is it used for?

The main ingredient of DULCOSOFT® is macrogol 4000, an osmotic laxative.

Macrogol 4000 has a high water-binding capacity. It serves as a carrier for the liquid (water) and retards the intestinal water absorption leading to an increased amount of water in the colon.

There, the hardened stool is softened and stool volume increases. This leads to increased bowel movement and eases defecation, supporting a natural feeling relief.

Macrogol 4000 has a purely physical mode of action: it is virtually not absorbed by the body and it is excreted unchanged.

DULCOSOFT® is used for:

- Symptomatic treatment of constipation
- Softening of hard stools

2. Before you take DULCOSOFT®

Do not take DULCOSOFT® in case of:

- Hypersensitivity to the active substance or to any of the excipients (please see composition)
- Severe inflammatory bowel disease (such as ulcerative colitis, Crohn's disease) or toxic megacolon
- Digestive perforation or risk of digestive perforation
- Ileus or suspicion of intestinal obstruction or symptomatic stenosis
- Painful abdominal syndromes of indeterminate cause

Do not take DULCOSOFT® if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking DULCOSOFT®.

Take special care

As with all laxatives, an organic disorder should have been ruled out before initiation of treatment. Without investigating the cause of constipation, DULCOSOFT® should not be taken on a continuous daily basis for an extended period of time. You should seek medical advice in case of persistent abdominal pain.

In case of diarrhoea, caution should be exercised in patients who are prone to a disturbance of water or electrolyte balance (e.g. elderly, patients with impaired hepatic or renal function or patients taking diuretics) and electrolyte control should be considered.

Allergic conditions (such as anaphylactic shock, anaphylactic reaction, angioedema, urticaria, rash and hypersensitivity) have been reported in patients taking products containing macrogol.

If you notice any of the above signs or symptoms, you should stop taking DULCOSOFT® and consult a doctor immediately.



Pregnancy and breast-feeding

DULCOSOFT® can be taken during pregnancy or breast-feeding since absorption of macrogol 4000 is negligible and for that reason no effects are anticipated. However, if you are pregnant or breast-feeding it is advisable to ask your doctor before using DULCOSOFT®.



Use in children

This product is not to be used by children under 2 years old.

Use in diabetics

DULCOSOFT® is suitable for diabetics. The solution does not contain sugar.

Suitable for patients on low sodium diets.

Gluten-free.

Taking DULCOSOFT® with other products

Macrogol 4000 increases the osmotic pressure in the gut, and thus might modify the intestinal absorption of other products concomitantly administered. In case you are taking other products please inform your doctor or pharmacist.

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3. How to take DULCOSOFT®

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

DULCOSOFT® is a flavourless solution. It can be directly mixed with a drink of your choice e.g. a glass of water or other liquid such as fruit juice or tea (about 150 ml).

Unless otherwise prescribed by the doctor, the usual dose is:

Adults and children aged 8 years and over:
20–40 ml solution daily (equivalent to 10–20 g macrogol 4000), preferably taken as a single dose in the morning.

For use in children under 8 years, consultation with a doctor is advised.

Children 4 to 7 years:
16–32 ml solution daily (equivalent to 8–16 g macrogol 4000), preferably taken as a single dose in the morning.

Children 2 to 3 years:
8–16 ml solution daily (equivalent to 4–8 g macrogol 4000), preferably taken as a single dose in the morning.

The dose is measured out using the measuring cup included in the pack and can be adjusted according to the effect obtained. Within the dose recommendation the dose can be adjusted to your individual needs and can be taken daily or every other day. The right dose is the lowest dose to produce regular soft stools.

Please note:

DULCOSOFT® usually takes 24–72 hours to work. Clinical studies show that when administered regularly, the frequency of bowel movements tends to be one movement per day.

If the constipation persists, the cause of constipation should be investigated. Children should not take DULCOSOFT® longer than 3 months.

If you take more than the recommended dose

Excessive doses of DULCOSOFT® are likely to cause diarrhoea, abdominal pain, abdominal distension and vomiting which resolves when treatment is interrupted or the dose is reduced. Large fluid losses due to diarrhoea or vomiting may require correction of electrolyte imbalance. You should contact a doctor in these circumstances.

If you forget to take DULCOSOFT®

Do not take a double dose of DULCOSOFT® if you forgot to take the previous dose.

4. Possible side effects

Side effects have generally been mild and transient.

Side effects in adults and children:

Diarrhoea, abdominal pain, abdominal distension, nausea, vomiting, faecal incontinence and flatulence. Rarely anaphylactic shock, anaphylactic reaction, angioedema, urticaria, rash, hypersensitivity may occur.

In case of diarrhoea, which usually disappears when treatment is stopped or the dose reduced, consider contacting your doctor as you may require treatment to prevent loss of salts (electrolytes) due to fluid loss.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store DULCOSOFT®

Keep medical devices out of the reach and sight of children.

Do not use DULCOSOFT® after the expiry date which is stated on the carton. The expiry date refers to the last date of that month.

Do not store DULCOSOFT® above 25°C and do not store it in the refrigerator. 

Use DULCOSOFT® liquid within 6 weeks of opening the bottle.

6. Further information

10 ml of DULCOSOFT® liquid contains 5 g of macrogol 4000.

The solution is available in packs containing 100 ml and 250 ml. Not all pack sizes may be marketed.

Other ingredients:

Potassium sorbate (preservative), macrogol 400, citric acid, purified water

CE 0482



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