

INSTRUCTIONS FOR USE

Dulcosoft® powder for oral solution

Please read this entire leaflet carefully as it contains important information. **Dulcosoft®** is available without a doctor's prescription.

- Keep this leaflet as you may need to consult it again.
- Ask your healthcare practitioner if you need more information or advice.
- Consult your healthcare worker if your symptoms worsen or do not improve.

Name of the medical device:

Dulcosoft® powder for oral solution.

What Dulcosoft® powder for solution contains:

The active ingredient in **Dulcosoft®** powder for solution is macrogol 4000. 1 sachet contains 10 g macrogol as powder for oral solution (no excipients).

Why is it important to use Dulcosoft® powder for solution?

The ingredient of **Dulcosoft®** laxative without excipients is macrogol 4000. Macrogol 4000 has a high water-binding capacity and serves as a carrier for the liquid (water), macrogol transports water directly into the colon. There, the hardened stool is softened and stool volume increases. This leads to increased bowel movement and eases the bowel movement. Macrogol 4000 has a purely physical mode of action; it is not absorbed by the body and excreted unchanged.

Intended use for Dulcosoft®:

- Symptomatic treatment of constipation
- Softening of hard stools.

Before you start using Dulcosoft® powder for solution:

Do not take **Dulcosoft®** in case of:

- Hypersensitivity to the active substance (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

Take special care with Dulcosoft® powder for solution:

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®**. 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. 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 imbalance (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.

If you need to thicken fluids in order to swallow them safely, **MACROGOL 4000 LAXATIVE WITHOUT EXCIPIENTS** may counteract the effect of the thickener.

Pregnancy and breastfeeding:

Dulcosoft® powder for solution can be taken during pregnancy or breastfeeding since the 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®**.

Using of other medicines with Dulcosoft® powder for solution:

Macrogol 4000 increases the osmotic pressure in the gut, and therefore might modify the intestinal absorption of other products concomitantly administered.

How to use Dulcosoft® powder for solution:**Use in children:**

This product is not to be used by children under 8 years old.

Use in diabetics:

Dulcosoft® is suitable for diabetics. The powder does not contain sugar.

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

Dulcosoft® has a neutral taste and can be dissolved in water or in a drink of your choice. Dissolve the contents of one sachet directly before intake in a glass of liquid (about 150 mL).

Adults and children aged 8 years and over:

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

1 – 2 sachets daily dissolved in liquid (equivalent to 10 – 20 g macrogol 4000), preferably taken as a single dose in the morning.

Children under 8 years should not use this product since other products are available that are better suited.

Within the dose recommendation the dose can be adjusted to your individual needs. It may range from one sachet every other day to two sachets per 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 Dulcosoft® should not be taken for longer than 30 days. If the constipation persists for longer, the cause of constipation should be investigated.

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® powder for solution:

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

Possible side effects:

Side effects have generally been mild and transient.

Side effects in adults:

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

Side effects in children:

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

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.

How to store Dulcosoft® powder for solution:

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.

Store at or below 25 °C.

STORE OUT OF REACH AND SIGHT OF CHILDREN.

What Dulcosoft® powder for solution looks like:

The active ingredient in **Dulcosoft®** is macrogol 4000.

1 sachet contains 10 g of macrogol 4000 with no added excipients.

The powder for oral solution is available in 10 g sachets. Sachets are packed inside containers containing 10 sachets, 20 sachets and 50 sachets. Not all sizes are marketed.

Applicant:

Opella Healthcare South Africa (Pty) Ltd 4th Floor,
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90 Bekker Road, Midrand, 1652

Manufactured by:

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