

# Dulcosoft Powder <sup>®</sup>

Macrogol 4000

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about Dulcosoft Powder.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you taking Dulcosoft Powder against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

### What Dulcosoft Powder is used for

Dulcosoft Powder belongs to a group of medicines called osmotic laxatives. It works by drawing water to your stool, which loosens the stool and increases stool volume, helping to overcome sluggish bowels gradually within 24 to 48 hours.

It is used for the treatment of constipation in adults and children aged 8 years and above.

Dulcosoft Powder is not absorbed into the bloodstream or broken down in the body.

### Before you take it

#### **When you must not take it**

**Do not take Dulcosoft Powder if you:**

- **Are allergic to it or any of the ingredients listed at the end of this leaflet.**

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

**Do not take Dulcosoft Powder if you have an existing severe intestinal disease such as:**

- inflammatory bowel disease (such as ulcerative colitis, Crohn's disease) or abnormal dilation of the bowel
- perforation of the bowel or risk of perforation of the bowel
- a blockage in the intestine
- painful belly of unknown cause

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Dulcosoft Powder is not recommended for children below the age of 8 years.

**Do not take it after the expiry date (exp) printed on the pack.**

**Do not take it if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged return it to your pharmacist for disposal

### **Before you start to take it**

**Tell your doctor or pharmacist if you have allergies to any other substances, such as foods, preservatives or dyes or any of the ingredients listed at the end of this leaflet.**

**Tell your doctor or pharmacist if you:**

- think you could be pregnant or you plan to become pregnant while taking Dulcosoft Powder
- are breastfeeding or planning to breastfeed
- have liver problems
- are taking diuretics (water tablets)
- are elderly as you may be at risk of low sodium (salt) or potassium levels in the blood.

### **Taking other medicines**

**Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop as these may interfere with Dulcosoft Powder.**

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Dulcosoft Powder.

### How to take it

**Follow all directions for use written on the medicine's label.**

**Do not take more than the recommended dose on the label or for a longer period of time.**

**Check with your doctor or pharmacist if you are not sure.**

### **How much to take**

#### **Adult**

The recommended adult dose is 1 to 2 sachets daily, preferably taken as a single dose in the morning.

#### **Children and adolescents**

In children 8 years and above, the recommended dose is 1-2 sachets daily, preferably taken as a single dose in the morning.

The daily dose should be adapted as required to produce regular soft stools and may range from one sachet every other day (especially in children) up to 2 sachets a day. If administered regularly, the frequency of bowel movements tends to be one movement per day.

### **How to take it**

**Dulcosoft Powder is a powder that you dissolve in a glass of water (125mL) and drink immediately.**

### **When to take it**

It does not matter if you take Dulcosoft Powder before or after food and it is recommended to be taken in the morning.

### **How long to take it**

**Dulcosoft Powder usually takes 24 to 48 hours to work.**

Improvement in the frequency of your bowel movements after taking Dulcosoft Powder can be maintained by keeping to a healthy lifestyle and diet.

### **If you forget to take it**

Take the next dose as soon as you remember.

**Do not take a double dose to make up for the dose that you missed.**

**If you are not sure what to do, ask your doctor or pharmacist.**

### **If you take too much (overdose)**

Taking too much Dulcosoft Powder may cause diarrhoea, which usually disappears when treatment is stopped or the dose reduced. If you have lost a large amount of fluids by diarrhoea or vomiting, contact your doctor as you may require treatment to prevent loss of salts (electrolytes due to fluid loss).

**Contact your doctor or the poisons information centre (telephone Australia 13 11 26 or New Zealand 0800 poison or 0800 764766), or go to accident and emergency at your nearest hospital, if you think you or anyone else may have taken too much Dulcosoft Powder.**

### **While you are taking it**

#### **Things you must do**

**Talk to your pharmacist or doctor if the symptoms worsen or not improve.**

Dulcosoft Powder can be taken during pregnancy and whilst breast feeding. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

#### **Things you must not do**

**Do not take more than the recommended dose unless your doctor or pharmacist tells you to.**

**Do not give this medicine to anyone else, even if they have the same condition as you.**

**Do not use this medicine to treat any other complaints unless your doctor or pharmacist tells you to.**

#### **Things that would be helpful for constipation**

It is generally recommended to consider healthy lifestyle measures such as adequate hydration, physical

activity, and increased natural fibre intake.

### **Side effects**

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Dulcosoft Powder.**

This medicine helps most people with constipation, but it may have unwanted side effects in a few people.

**You should go straight to hospital if you have difficulty in breathing, start to look flushed, or have any other symptom that you think might mean you are having a serious allergic reaction.**

**Tell your doctor as soon as possible if you notice any of the following:**

- Allergic reactions (rash, hives, swelling of the face or throat, breathing difficulties, faintness or collapse).

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- Stomach pain or discomfort
- Inability to retain stools in the rectum
- Bloating
- Nausea
- Diarrhoea
- Vomiting
- Gas
- Urgent need to go to the toilet

Other side effects not listed above may occur in some consumers.

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

**Tell your doctor or pharmacist if you notice any other side effects.**

**Ask your doctor or pharmacist to answer any questions you may have.**

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## After using it

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### **Storage**

**Keep the medicine in a cool dry place where the temperature stays below 25°C. Store in its original container to protect from light.**

**Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car on hot days or on window sills.**

Heat and dampness can destroy some medicines.

**Keep it where children cannot reach it.**

### **Disposal**

**Ask your pharmacist what to do with any medicine that is left over after the expiry date has passed.**

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## Product description

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### **What it looks like**

Dulcosoft Powder is a white powder and the reconstituted solution is colourless and clear.

Pack sizes of 10 or 20 sachets are available. Not all pack sizes may be marketed.

### **Ingredients**

#### **Active ingredient:**

The active ingredient, macrogol 4000. Each sachet contains 10g.

### **Sponsor**

Sanofi Consumer Healthcare

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