

## **Package leaflet: Information for the user**

### **Dulcosoft 10 g powder for oral solution in sachet Macrogol 4000**

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

#### **1. What Dulcosoft is and what it is used for**

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

Dulcosoft is not absorbed into the bloodstream or broken down in the body. It is used for the treatment of constipation in adults and children aged 8 years and above.

The treatment of constipation with any medicine should only be in addition to a healthy lifestyle and diet.

#### **2. What you need to know before you take Dulcosoft**

##### **Do not take Dulcosoft:**

- if you are allergic to macrogol (polyethylene glycol) or any of the other ingredients of this medicine (listed in section 6).
- 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
  - intestinal obstruction or suspicion of intestinal obstruction or symptomatic narrowing of the bowel
  - painful belly of unknown cause

##### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking Dulcosoft

Without investigating the cause of constipation, Dulcosoft should not be taken on a continuous daily basis for an extended period of time. Medical advice should be sought in case the symptoms persist for more than 2 weeks or in case of persistent abdominal pain.

Cases of allergic reactions involving rash, hives and swelling of the face or throat have been reported in adults after taking products containing macrogol (polyethylene glycol). Isolated severe allergic reactions have been reported causing faintness, collapse or breathing difficulties and feeling generally unwell. If you experience any of these symptoms you should stop taking Dulcosoft and seek medical help immediately.

If you experience any of these symptoms you should stop taking Dulcosoft and seek medical help immediately.

As this medicine can sometimes cause diarrhoea, check with a doctor or pharmacist before taking this medicine if you:

- have impaired liver or kidney function
- are taking diuretics (water tablets) or are elderly as you may be at risk of low sodium (salt) or potassium levels in the blood

### **Children**

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

### **Other medicines and Dulcosoft**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any **other medicines**, since the way this medicine works may influence the intertinal absorption of other medicines.

### **Pregnancy and breast-feeding**

Dulcosoft 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.

### **Driving and using machines**

No studies on the effects on the ability to drive and use machines have been performed.

### **Dulcosoft contains sorbitol**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## **3. How to take Dulcosoft**

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your your doctor, pharmacist or nurse if you are not sure.

The recommended dose is 1 to 2 sachets daily, preferably taken as a single dose in the morning. Dulcosoft is a powder that you dissolve in a glass of water (125 ml) and drink immediately.

In case the symptoms persist or get worst, a physician should be consulted.

### **Use in children and adolescents**

In children 8 years and above, the recommended dose is 1 to 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.

Also please note:

- Dulcosoft usually takes 24 to 48 hours to work
- Improvement in the frequency of your bowel movements after taking Dulcosoft can be maintained by keeping to a healthy lifestyle and diet.
- Talk to your pharmacist or doctor if the symptoms worsen or do not improve

#### **If you take more Dulcosoft than you should**

Taking too much Dulcosoft 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.

#### **If you forget to take Dulcosoft>**

Take the next dose as soon as you remember.

Do not take a double dose to make up for a forgotten dose.

If you do not feel better or if you feel worse after 14 days you must contact a doctor.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

### **Serious side effects**

Whilst taking Dulcosoft, if you develop any of the following symptoms **you should contact your doctor immediately**:

- Allergic reactions (rash, hives, swelling of the face or throat, breathing difficulties, faintness or collapse) (frequency not known, frequency cannot be estimated from the available data)

### **Other side effects**

The side effects that are usually mild and do not last long include:

However if any of the following side effects gets serious, contact your doctor as soon as possible.

#### **In adults:**

**Common (may affect up to 1 in 10 people):**

- Abdominal pain
- Bloating
- Nausea
- Diarrhoea

**Uncommon (may affect up to 1 in 100 people):**

- Vomiting
- Urgent need to go to the toilet

Not known (frequency cannot be estimated from the available data):

- Passing gas

*In children:*

Common (may affect up to 1 in 10 people):

- Abdominal pain
- Diarrhoea

Uncommon (may affect up to 1 in 100 people):

- Vomiting
- Bloating
- Nausea

Not known (frequency cannot be estimated from the available data):

- Passing gas

### **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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

ADR Reporting

The Medicines Authority  
Post-Licensing Directorate  
Sir Temi Żammit Buildings,  
Malta Life Sciences Park,  
San Ġwann SGN 3000  
Malta

Website: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)

e-mail: [postlicensing.medicinesauthority@gov.mt](mailto:postlicensing.medicinesauthority@gov.mt)

## **5. How to store Dulcosoft**

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

Do not store above 30°C. Store in its original container to protect from light.

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 Dulcosoft contains

- The active substance is macrogol 4000 (polyethylene glycol). Each sachet contains 10 g.
- The other ingredient(s) are magnesium citrate (anhydrous), citric acid (anhydrous), calcium citrate, acesulfame K, potassium chloride (with 0.9% silica colloidal, anhydrous), lemon-grapefruit flavour (contains natural lemon oil, liquid flavour grapefruit, powder flavour maracuja, powder flavour grenadine/raspberry, mannitol (E421), gluconolactone (E575), sorbitol (E420), anhydrous silica colloidal (E551)). See section 2 “Dulcosoft contains sorbitol (E420)”.

### What Dulcosoft looks like and contents of the pack

Dulcosoft is a white powder, free of large agglomerates, with an odour and taste of lemon, packed in an Aluminium / Paper sachet. The reconstituted solution is colourless & clear.

Pack sizes of 10 or 20 sachets.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

#### Marketing Authorisation Holder

Sanofi Malta Ltd  
St Julian's Road  
San Gwann SGN 2805  
Malta

#### Manufacturer

Hermes Pharma Ges.m.b.H.  
Allgäu 36, A-9400 Wolfsberg,  
Austria

**This medicinal product is authorised in the Member States of the EEA under the following names:**

<b>Austria:</b>	Dulcosoft 10 g Pulver zur Herstellung einer Lösung zum Einnehmen in Beutel
<b>Belgium</b>	Dulcosoft 10 g, Poudre pour solution buvable en sachet Dulcosoft 10g Poeder voor drank in zakje Dulcosoft 10g Pulver zur Herstellung einer Lösung zum Einnehmen in Beutel
<b>Bulgaria:</b>	Dulcosoft 10 g Прах за перорален разтвор в саше
<b>Czech Republic:</b>	Macrolax 10 g
<b>Cyprus:</b>	Dulcosoft 10 g Κόνις για πόσιμο διάλυμα σε φακελίσκο
<b>Denmark:</b>	Dulcosoft
<b>Greece:</b>	Dulcosoft 10 g Κόνις για πόσιμο διάλυμα σε φακελίσκο
<b>Finland:</b>	Dulcosoft 10 g Jauhe oraaliliuosta varten, annospussi
<b>France:</b>	Laxosoft 10 g, Poudre pour solution buvable en sachet
<b>Ireland:</b>	Macrosoft 10 g Powder for Oral Solution in Sachet
<b>Italy:</b>	Dulcosoft
<b>Luxembourg:</b>	Dulcosoft 10 g Poudre pour solution buvable en sachet
<b>Malta:</b>	Dulcosoft 10 g Powder for oral solution in sachet
<b>Netherlands:</b>	Dulcosoft, 10 g Poeder voor drank in zakje
<b>Portugal:</b>	Dulcosoft
<b>Romania:</b>	Macrogol PharOS 10 g Pulbere pentru soluție orală în plic

**Sweden:** Dulcosoft, 10 g Ppulver till oral lösning i dospåse  
**Spain:** Macrolaxo Laxomacro 10 g Polvo para solución oral en sobre EFG  
**United Kingdom:** Dulcosoft 10 g powder for oral solution in sachet

**This leaflet was last revised in August 2017**