

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).

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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
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Manufactured by:

Fairpharm Vertriebs GmbH
Am Krebsenbach 5 - 7
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GEBRUIKSAANWYSINGS

Dulcosoft® poeier vir mondlike oplossing

Lees hierdie inligtingsblad aandagtydig deur want dit bevat belangrike inligting.

Dulcosoft® is beskikbaar sonder voorskrif van 'n dokter.

- Hou hierdie inligtingsblad, want dit mag nodig wees om dit later weer te lees.
- Indien jy verdere inligting of advies nodig het, vra jou gesondheidsspraktsyn indien jou simptome versleg of nie verbeter nie.

Naam van die mediese toestel:

Dulcosoft® poeier vir mondlike oplossing.

Wat Dulcosoft® poeier vir oplossing bevat:

Die aktiewe bestanddeel in **Dulcosoft®** poeier vir oplossing is makrogol 4000. 1 sakkie bevat 10 g makrogol as poeier vir mondlike oplossing (geen hulpstowwe nie).

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Hoekom is dit belangrik om Dulcosoft® poeier vir oplossing te gebruik?

Dulcosoft® lakseermiddel bevat die bestanddeel makrogol 4000, sonder enige onaktiewe bestanddele. Makrogol 4000 het 'n groot kapasiteit om water te bind, en dien as 'n draer vir die vloeistof (water).

Makrogol vervoer water direk in die kolon in. Daar word die verharde stolgang versag en die volume van die stolgang vergroot. Dit veroorsaak meer onlastiging en vergemaklik die ontlasting. Makrogol 4000 werk op 'n bloot fisiese manier; dit word nie deur die liggaam geabsorbeer nie en word onveranderd uitgeskei.

Waarvoor Dulcosoft® gebruik kan word:

- Simptomatiese behandeling van hardlywigheid
- Versagting van harde stolgange.

Voordat jy begin om Dulcosoft® poeier vir oplossing te gebruik: Moenie **Dulcosoft®** neem indien die volgende voorkom nie:

- Hipersensitiwiteit vir die aktiewe bestanddeel (verwys asseblief na die samestelling)
- Erge inflammatoriese dermsiekte (soos ulceratiewe kolitis, Crohn se siekte) of toksiiese megakolon
- Perforasie van die spysverteringskanal, risiko daarvan
- Ileus of vermoedelike blokkasie van die dermankaan of simptomatiese vernouing
- Pynlike sindrome van die buik waarvan die oorsaak nie vasegestel is nie.

Neem spesiale sorg met Dulcosoft® poeier vir oplossing:

Moenie **Dulcosoft®** neem indien enige van bogenoemde op jou van toepassing is nie. Indien jy onseker is, bespreek dit met jou dokter of apteker voordat jy **Dulcosoft®** neem. Soos met alle lakseermiddels, moet 'n organiese versteuring uitgeskakel word vooraf met behandelung begin word. **Dulcosoft®** moenie op 'n aaneenlopende daagliks basis vir 'n verlengde tydperk gebruik word sonder dat die oorsaak van die hardlywigheid ondersoek is nie. Verkry mediese advies in geval van volgehoue buikpyn.

Wees versigtig by pasiënte wat geneig is tot 'n versteuring van water- of elektrolietbalans indien diarree voorkom (bv. bejaardes, pasiënte met belemmerde lever- of nierfunksie, of pasiënte wat diureтика neem) en dit moet oorweeg word om elektrolyte te kontroleer. Allergiese toestande (soos anafilaktiese skok, anafilaktiese reaksie, angio-edeme, urtikarie, uitslag en hipersensitiwiteit) is gerapporteer by pasiënte wat produkneem wat makrogol bevat. Indien jy enige van bogenoemde tekens of simptome opmerk, moet jy ophou om **Dulcosoft®** te neem en onmiddellik 'n dokter raadpleeg. As jy vloeistowwe moet verdik om dit veilig te sluk, kan **MACROGOL 4000 Lakseermiddel SONDER HULPSTOF** die effek van die verdikkingsmiddel teewerker.

Swangerskap en borsvoeding:

Dulcosoft® poeier vir oplossing kan tydens swangerskap en borsvoeding gebruik word, aangesien die absorpsie van makrogol 4000 weglegbaar is en gevoldiglik word geen effekte verwag nie. Indien jy swanger is of borsvoed, is dit egter raadsaam om eers jou dokter te vra voordat jy **Dulcosoft®** gebruik.

Gebruik van ander medisyne saam met Dulcosoft® poeier vir oplossing:

Makrogol 4000 verhoog die osmotiese druk in die dermankaan, en mag gevoldiglik die intestinale absorpsie van ander produkte wat terselfdertyd toegedien word wysig.

Hoe om Dulcosoft® poeier vir oplossing te gebruik: Gebruik by kinders

Hierdie produk moenie gebruik word deur kinders jonger as die ouderdom van 8 jaar nie.

Gebruik by diabete:

Dulcosoft® is geskik vir diabete. Die poeier bevat nie suiker nie.

Neem **Dulcosoft®** altyd presies soos wat in hierdie inligtingsblad aangedui word. Indien jy onseker is, vra gerus jou dokter of apteker.

Dulcosoft® het 'n neutrale smaak en kan in water of in 'n drankie van jou keuse opgelos word. Los die inhoud van een sakkie in 'n glas vloeistof (ongeveer 150 mL) op, net voor jy dit inneem.

Volvassenes en kinders 8 jaar en ouer:

Behalwe indien anders voorgeskryf is deur die dokter, is die gebruikelike dosis:

1 – 2 sakkies daagliks, opgelos in vloeistof (gelykstaande aan 10 – 20 g makrogol 4000), verkieks as 'n enkele dosis soggoed geneem.

Kinders jonger as 8 jaar moenie hierdie produk gebruik nie,

aangesien daar ander produkte beskikbaar is wat meer geskik is.

Die dosis kan aangepas word by jou individuele behoeftes, binne die aanbevole dosisreikwydte. Dit kan wissel van een sakkie elke tweede dag, tot twee sakkies per dag. Die korrekte dosis is die laagste dosis wat gerealiseerde, sagte stolgangs bewerkstellig.

Let op:

Dulcosoft® neem gewoonlik 24 – 72 uur om te werk. Kliniese studies toon dat

Dulcosoft® nie vir langer as 30 dae geneem behoort te word nie. Indien die hardlywigheid langer aanhou, moet die oorsaak van die hardlywigheid ondersoek word.

Indien jy meer as die aanbevole dosis neem:

Oormatige dosisse **Dulcosoft®** sal waarskynlik diarree, buikpyn, buikopsetting en braking veroorsaak, wat opklaar wanneer behandelung onderbreek word, of wanneer die dosis verlaag word.

Verlies van groot hoeveelhede vloeistof weens diarree of braking mag vereis dat die wanbalans van elektrolyte herstel word. Jy moet 'n dokter kontak onder hierdie omstandighede.

Indien jy vergeet om Dulcosoft® poeier vir oplossing te neem: Moenie 'n dubbele dosis **Dulcosoft®** neem indien jy vergeet het om die vorige dosis te neem nie.

Moontlike newe-effekte:

Newe-effekte was oor die algemeen gering en van verbygaande aard.

Newe-effekte by volwassenes:

Diarree, buikpyn, buikopsetting, naarheid, braking, fekale inkontinenste en flatulensie. By uitsondering mag anafilaktiese skok, anafilaktiese reaksie, angio-edeme, urtikarie, uitslag, of hipersensitiwiteit voorkom.

Newe-effekte by kinders:

Diarree, buikpyn, buikopsetting, braking, naarheid en flatulensie. By uitsondering mag anafilaktiese skok, anafilaktiese reaksie, angio-edeme, urtikarie, uitslag, of hipersensitiwiteit voorkom.

Indien enige van die newe-effekte ernstig raak, of indien jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad gelys word nie, lig asseblief jou dokter of apteker in.

Hoe om Dulcosoft® poeier vir oplossing te bêre:

Moenie **Dulcosoft®** ná die vervaldatum wat op die karton voorkom, gebruik nie. Die vervaldatum verwys na die laaste dag van daardie maand.

Bêre by of onder 25 °C.

HOU BUISTE BEREIK EN SIG VAN KINDERS.

Hoe Dulcosoft® poeier vir oplossing lyk:

Die aktiewe bestanddeel in **Dulcosoft®** is makrogol 4000 poeier. 1 sakkie bevat 10 g **Dulcosoft®** poeier vir oplossing, met geen bygevoegde hulpmiddels nie. Die poeier vir mondlike oplossing is beskikbaar in 10 g sakkies. Sakkies word verpak in hours wat 10 sakkies, 20 sakkies en 50 sakkies bevat. Nie al die groottes word bemark nie.

Applikant:

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