AUSTRALIAN PRODUCT INFORMATION – DULCOSOFT (MACROGOL 4000)

1 NAME OF THE MEDICINE

Macrogol 4000

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

DULCOSOFT sachet contains 10 g of macrogol 4000 per sachet.

3 PHARMACEUTICAL FORM

Powder for oral solution in sachet.

White powder, free of large agglomerates, packed in a sachet for the preparation of an oral solution.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

For the relief from constipation. Treatment of chronic constipation.

4.2 DOSE AND METHOD OF ADMINISTRATION

Dose

Adults

1 to 2 sachets (10 to 20 g macrogol 4000) per day, preferably taken as a single dose in the morning.

Paediatric population

~ **Children ≥8 years and adolescents:** 1 to 2 sachets (10 to 20 g macrogol 4000) per day, preferably taken as a single dose in the morning.

~ **Children (<8 years):** DULCOSOFT is not recommended for use in children below the age of 8 years.

Method of administration

Oral use. Each sachet should be dissolved in 125 ml of water just before use.

It is recommended to start with the lowest dose. The dose should be adjusted up or down as required to produce regular soft stools.

Adults & Children 8 years and over:
Start by taking 1 sachet a day, dissolved in a glass of water or fruit juice
If needed increase to 2 sachets a day, taken as a single dose preferably in the morning
Continue to take it until your bowel movements return to normal.
DulcoSoft works within 24 to 48 hours.

Adjustment dose may be required to produce regular soft stools:
Children 8 to 12 years:
1 sachet on alternate days to a maximum of 3 sachets each day.
Should be limited to 3 months except under medical supervision.
Adults and children over 12 years:
1 sachet on alternate days to a maximum of 4 sachets each day.

To be taken at least 2 hours before or 2 hours after other medication to avoid possibility of reducing the absorption of other medicines.

The maximum recommended daily dose can also be divided equally into singular doses to be taken in the morning and evening.

The effect of DULCOSOFT becomes usually apparent within 24 to 48 hours after its initial administration. If administered regularly, the frequency of bowel movements tends to be one movement per day.

Duration of treatment

In children ≥ 8 years and adolescents, treatment should not exceed 3 months unless supervised by a physician due to a limitation of clinical data for treatment lasting longer than 3 months.

4.3 CONTRAINDICATIONS

- Hypersensitivity to the active substance
- 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

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Precaution before and during treatment

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. The patient is instructed to seek medical advice in case of persistent abdominal pain.

Risks in specific populations

In case of diarrhea and/or vomiting, 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 reactions

Allergic conditions (such as anaphylactic shock, anaphylactic reaction, angioedema, urticaria, rash and hypersensitivity) have been reported with drugs containing macrogol (polyethylene glycol).

Use in the elderly

In case of diarrhoea and/or vomiting, caution should be exercised in elderly patients.

Paediatric use

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

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Macrogol 4000 increases the osmotic pressure in the gut, and thus might modify the intestinal absorption of drugs concomitantly administered.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No studies on the effect on human fertility have been conducted. No effects on fertility are anticipated, since systemic exposure to macrogol 4000 is negligible. (see Section 5.2 PHARMACOKINETIC PROPERTIES).

Use in pregnancy

Category B1

Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus having been observed.

A healthcare professional should be consulted before using DULCOSOFT in pregnancy.

Use in lactation

A healthcare professional should be consulted before using DULCOSOFT during lactation.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Undesirable effects are listed under headings of frequency using the following conventions:

Very common: ≥1/10, Common: ≥1/100 to <1/10, Uncommon: ≥1/1,000 to <1/100, Rare: ≥1/10,000 to <1/1,000, Very rare: <1/10,000, Not known: cannot be estimated from the available data

Tabulated list of adverse reactions

Adult:

In clinical trials, side effects have been minor and transitory and have mainly concerned the gastrointestinal system.

System Organ Class	Adverse Drug Reaction
Immune system disorders	Frequency not known: anaphylactic shock, anaphylactic reaction, angioedema, urticaria, rash, hypersensitivity
Gastro-intestinal disorders	Common: diarrhoea, abdominal pain, abdominal distension, nausea Uncommon: vomiting, faecal incontinence Frequency not known: flatulence

Paediatric population

As in adult population, adverse reactions have generally been minor and transitory and have mainly concerned the gastrointestinal system.

Frequency type and severity of adverse reactions in children have been observed to be comparable to adults.

System Organ Class	Adverse Drug Reaction
Immune system disorders	Frequency not known: Anaphylactic shock, anaphylactic reaction, angioedema, urticaria, rash, hypersensitivity
Gastro-intestinal disorders	Common: diarrhoea, abdominal pain Uncommon: abdominal distension, vomiting, nausea Frequency not known: flatulence

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at http://www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Symptoms

Overdose and/or abuse may lead to diarrhoea, abdominal pain, abdominal distention and vomiting which disappears when treatment is temporarily interrupted or the dose reduced.

Therapy

Excessive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances.

For information on the management of overdose, contact the Poison Information Centre on 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: Laxatives, osmotically acting laxatives, ATC code: A06AD15

Mechanism of action

Macrogol 4000 softens the stool by retaining water molecules. Thereby it increases the stool volume, which triggers colon motility via neuromuscular pathways. The physiological consequence is an improved propulsive colonic transportation of the softened stools which facilitates defaecation.

Different doses of macrogol are shown to have different effects on intestinal function. In healthy volunteers, low doses increase stool weight without modifying oro-anal transit time. In constipated patients, low doses decrease stool consistency, increase stool frequency, and facilitate stool evacuation without modifying stool weight and colonic transit time. Bloating

produced by the administration of macrogol is usually due to intestinal distention by water binding.

Clinical trials

No data available

5.2 PHARMACOKINETIC PROPERTIES

Absorption

Macrogol 4000 is only minimally absorbed, i.e. 0.05%, from the intestine of healthy subjects following an oral administration of 2 g.

Metabolism

Like other polyethylene glycols with molecular masses exceeding 3000 Da, macrogol 4000 does not undergo any intestinal enzymatic degradation or bacterial metabolism.

Excretion

Urinary excretion of macrogols occurs through passive glomerular filtration. Macrogol 4000 is excreted unchanged in urine with mean urinary recovery ranging from 0.05% to 0.46%. Macrogol 4000 is eliminated in the faeces with very high recovery rates ranging between 93% and 100%.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

Toxicological studies in different species of animals did not reveal any signs of systemic or local gastrointestinal toxicity of macrogol 4000. Macrogol 4000 had no teratogenic, mutagenic, nor carcinogenic effect. No studies on fertility are available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

None.

6.2 INCOMPATIBILITIES

Macrogol 4000 increases the osmotic pressure in the gut, and thus might modify the intestinal absorption of drugs concomitantly administered.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Do not store above 25°C.

Store in its original container to protect from light.

6.5 NATURE AND CONTENTS OF CONTAINER

Sachet (Aluminium / Paper)

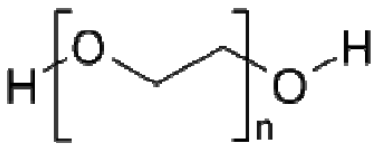
Unidose sachets in packs of 10 or 20 sachets.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical structure



CAS number

25322-68-3

7 MEDICINE SCHEDULE (POISONS STANDARD)

Not scheduled.

8 SPONSOR

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9 DATE OF FIRST APPROVAL

14 May 2020

10 DATE OF REVISION