AUSTRALIAN PRODUCT INFORMATION

MOLAXOLE®

macrogol 3350/sodium chloride/sodium bicarbonate/potassium chloride powder for oral solution

1 NAME OF THE MEDICINE

macrogol 3350, sodium chloride, sodium bicarbonate and potassium chloride

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 13.8 g sachet of MOLAXOLE contains:
Macrogol 3350 13.125 g
Sodium chloride 350.7 mg
Sodium bicarbonate 178.5 mg
Potassium chloride 46.6 mg

When it is made into a drink with 125 mL water, each sachet provides:
Sodium 65 mmol/L
Chloride 53 mmol/L
Bicarbonate 17 mmol/L
Potassium 5.4 mmol/L

Excipients with known effect: Each sachet contains 26 mg of potassium and 187 mg of sodium.

For the full list of excipients, see Section 6.1 LIST OF EXCIPIENTS.

3 PHARMACEUTICAL FORM

White crystalline powder for oral solution.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

For effective relief from constipation, treatment of chronic constipation and treatment of faecal impaction defined as refractory constipation with faecal loading of the rectum and/or colon confirmed by physical examination of abdomen and rectum.

4.2 DOSE AND METHOD OF ADMINISTRATION

Dosage in adults and children over 12 years:

Constipation: The dose is 1 sachet daily. This may be increased up to 3 sachets daily, if required.

Faecal Impaction as diagnosed by a doctor: 8 sachets daily, consumed within 6 hours. A course of treatment for faecal impaction does not normally exceed 3 days.

Patients with impaired cardiovascular function: For the treatment of faecal impaction the dose should be divided so that no more than two sachets are taken in any one hour.

Patients with renal insufficiency: No dosage change is necessary for treatment of either constipation or faecal impaction.

Administration:

For oral administration. Each sachet should be dissolved in 125 mL water. For faecal impaction, 8 sachets may be dissolved in 1 litre of water and stored well covered in the fridge for up to 6 hours (see Section 6.4 SPECIAL PRECAUTIONS FOR STORAGE).

4.3 CONTRAINDICATIONS

Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, ileus and severe inflammatory conditions of the intestinal tract, such as Crohn's disease, ulcerative colitis and toxic megacolon. Known hypersensitivity to the active substances or any of the excipients.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Adverse reactions are possible as described under Section 4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS). If patients develop any symptoms indicating shifts of fluid/electrolytes (e.g. oedema, shortness of breath, increasing fatigue, dehydration, cardiac failure) MOLAXOLE should be stopped immediately and electrolytes measured, and any abnormality should be treated appropriately.

The absorption of other medicinal products could transiently be reduced due to a decrease in gastrointestinal transit time induced by MOLAXOLE (see Section 4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS).

As with all laxatives, prolonged use is undesirable and may lead to dependence. Patients should be advised to drink plenty of water and increase fibre in the diet except in cases of medication-induced constipation.

Use in Renal Impairment

See Section 4.2 DOSE AND METHOD OF ADMINISTRATION – Patients with renal insufficiency.

Use in the Elderly

No data available.

Paediatric Use

Not recommended for children below 12 years of age, as there is no clinical data for use of MOLAXOLE in children below 12 years of age.

Effects on Laboratory Tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

There is a possibility that the absorption of other medicinal products could be transiently reduced during use with MOLAXOLE (see Section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE). There have been isolated reports of decreased efficacy with some concomitantly administered medicinal products, e.g. anti-epileptics. A theoretical potential also exists for decreased absorption (rate and extent) of drugs which are generally poorly absorbed or are contained in sustained or modified release dosage forms. This is more likely to occur if MOLAXOLE is overdosed to induce watery diarrhoea.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on Fertility

No data available.

Use in Pregnancy (Category B1)

There were no direct embryotoxic or teratogenic effects in rats at maternally toxic doses up to 40 g/kg/day, 51x the maximum recommended dose in humans for chronic constipation and 19x for faecal impaction.

Indirect effects, including reduction in foetal and placental weights, reduced foetal viability and abortions, were noted in the rabbit at doses below the maximum recommended human dose. Rabbits are particularly

sensitive to the effects of GI acting substances, and the findings are considered most likely a reflection of poor maternal condition as a result of an exaggerated pharmacodynamic response rather than direct embryofoetal toxicity. There was no indication of a teratogenic effect.

Use in Lactation

No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to macrogol 3350 is negligible. MOLAXOLE can be used during breast-feeding.

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)

Reactions related to the gastrointestinal tract occur most commonly. These reactions may occur as a consequence of expansion of the contents of the gastrointestinal tract, and an increase in motility due to the pharmacologic effects of MOLAXOLE. Diarrhoea usually responds to dose reduction.

System Order Class	Adverse Event
Immune system disorders	Allergic reactions, including anaphylaxis, angioedema, dyspnoea, rash, erythema, urticaria, and pruritus.
Metabolism and nutrition disorders	Electrolyte disturbances, particularly hyperkalaemia and hypokalaemia.
Nervous system disorders	Headache
Gastrointestinal disorders	Abdominal pain, diarrhoea, vomiting, nausea, dyspepsia, abdominal distension, borborygmi, flatulence, anal discomfort.
General disorders and administration site conditions	Peripheral oedema
Skin and subcutaneous tissue disorders	Allergic skin reactions including angioedema, urticaria, pruritus, rash, erythema.

Reporting Suspected Adverse Effects

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 www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Severe pain or distention can be treated by nasogastric aspiration. Extensive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia) or 0800 POISON or 0800 764 766 (New Zealand).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of Action

Macrogol 3350 exerts an osmotic action in the gut, which induces a laxative effect. Macrogol 3350 increases the stool volume, which triggers colon motility via neuromuscular pathways. The physiological consequence is an improved propulsive colonic transportation of the softened stools and a facilitation of the defaecation.

Electrolytes combined with macrogol 3350 are exchanged across the intestinal barrier (mucosa) with serum electrolytes and excreted in faecal water without net gain or loss of sodium, potassium and water.

Clinical Trials

The laxative action of macrogol 3350 has a time course which will vary according to the severity of the constipation being treated. Faecal Impaction – In a non-comparative study in 27 adult patients, macrogol 3350, sodium chloride, sodium bicarbonate and potassium chloride cleared the faecal impaction in 12/27 (44%) after 1 day's treatment, 23/27 (85%) after 2 day's treatment and 24/27 (89%) at the end of 3 days. Controlled comparative studies have not been performed with other treatments (e.g. enemas).

5.2 PHARMACOKINETIC PROPERTIES

Macrogol 3350 is unchanged along the gut. It is virtually unabsorbed from the gastrointestinal tract. Any macrogol 3350 that is absorbed is excreted via the urine.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

Preclinical studies provide evidence that macrogol 3350 has no significant systemic toxicity potential, based on conventional studies of pharmacology, repeated dose toxicity, genotoxicity and toxicity to reproduction.

Carcinogenicity

There are long-term animal toxicity and carcinogenicity studies involving macrogol 3350. Results from these and other toxicity studies using high levels of orally administered high molecular weight macrogols provide evidence of safety at the recommended therapeutic dose.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Lemon flavour and acesulfame potassium as a sweetener.

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

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

Store below 25°C. Store in the original package in order to protect from moisture.

Once you have made up the MOLAXOLE solution, it may be stored well covered in the fridge at 2°C to 8°C (Do not freeze). Throw away any solution not used within a 6 hour period.

6.5 NATURE AND CONTENTS OF CONTAINER

There are 2, 6, 8, 10, 20 or 30 sachets in a box. The sachet material is Al laminated with LDPE/paper.

Not all pack sizes are marketed in Australia.

Australian Register of Therapeutic Goods (ARTG)
AUST R 213018 – MOLAXOLE powder for oral solution sachet

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

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

6.7 PHYSICOCHEMICAL PROPERTIES

Not available.

7 MEDICINE SCHEDULE (POISONS STANDARD)

Unscheduled

8 SPONSOR

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9 DATE OF FIRST APPROVAL

31 July 2013

10 DATE OF REVISION

05/07/2022

Summary Table of Changes

Section Changed	Summary of New Information
All	Editorial update
6.5	Insert AUST R number
8	Sponsor details update

MOLAXOLE® is a Viatris company trade mark

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