

AUSTRALIAN PRODUCT INFORMATION – GO-KIT™ (BISACODYL, MAGNESIUM CARBONATE HYDRATE, CITRIC ACID)

1 NAME OF MEDICINE

Bisacodyl Tablets

Bisacodyl

Magnesium Citrate Sachet

Magnesium carbonate hydrate

Citric acid

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

GO-KIT is a medicine kit containing:

- Three (3) yellow Bisacodyl 5 mg Tablets. Each Bisacodyl tablet contains bisacodyl 5 mg, as the active ingredient.
- One (1) Magnesium Citrate 21.5 g sachet. Each sachet contains magnesium carbonate hydrate 7.2 g and citric acid 14.3 g, as the active ingredients.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Bisacodyl Tablets: Enteric-coated tablets. For oral use.

Bisacodyl is a round yellow enteric-coated tablet.

Magnesium Citrate Sachet: Powder for solution. For oral use.

The sachet contains an effervescent white crystalline powder composed of magnesium carbonate and citric acid, which together form magnesium citrate in solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

GO-KIT is indicated for bowel emptying and cleansing in conjunction with barium meal, barium enema x-ray examination, air contrast examination, and prior to intravenous pyelograms (IVP).

4.2 Dose and method of administration

The Bisacodyl 5 mg Tablets should be taken whole and not crushed or chewed.

Prior to the procedure

During the day, patients should drink at least one glass (approx. 250 mL) of Recommended Clear Fluids (see **APPENDIX I**), in addition to the water taken with GO-KIT, each hour until bedtime to maintain adequate hydration. It is recommended that patients follow a modified diet, such as a low-fibre diet, up until they take the medication. Upon taking the medication, the patient may only have Recommended Clear Fluids.

Preparation of the solution

Dissolve the contents of the 21.5 g Magnesium Citrate sachet, by slowly adding the powder in approximately 250 mL of warm water (not boiling) using a suitable food grade container. The solution may appear cloudy, may become hot and produce effervescence upon reconstitution. Stir gently until the effervescence ceases. If desired, the solution may be refrigerated after reconstitution. The reconstituted solution should be ingested within 24 hours of reconstitution.

Recommended dosing regimen

Below is an example of a dosing regimen. The dosing regimen may be adjusted by a Healthcare Professional as required.

First Dose: Bisacodyl tablets (taken at 12:00 PM)

Take the three (3) Bisacodyl Tablets with one full glass (approx. 250 mL) of water.

Second Dose: Magnesium Citrate sachet (taken at 6:00 PM)

The solution should be ingested slowly but completely. This should be followed by drinking adequate glasses of water or Recommended Clear Fluids, at least one (1) glass every hour after that.

4.3 Contraindications

GO-KIT should not be used by patients with an acute abdominal conditions such as appendicitis, gastrointestinal obstruction, gastric retention, bowel perforation (frank or suspected), toxic megacolon, toxic colitis, ileus, body weight less than 20 kg, severe dehydration, or hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Identified precautions

Use with caution in patients with inflammatory bowel disease (IBD), marked bloody diarrhoea, pre-existing electrolyte disturbances, congestive heart failure, diabetes and those with a stoma.

GO-KIT is likely to cause transient hypovolaemia, hence adequate fluid intake or replacement should be ensured (see section 4.2 Dosage and method of administration).

GO-KIT should be administered with caution in patients with congestive heart failure and pre-existing electrolyte disturbances. These patients should be monitored.

GO-KIT should be administered with caution to patients using calcium channel blockers, diuretics or other medications that may affect electrolyte serum levels and exacerbate volume depletion. These patients should be monitored.

GO-KIT may cause bloating, distension or abdominal pain.

Use in hepatic impairment

No data is available.

Use in renal impairment

Patients with kidney disease or impaired renal function should be monitored.

Use in the elderly

Caution should be exercised in the elderly as dehydration and electrolyte depletion may occur. Elderly patients must receive adequate fluids during administration.

Paediatric use

The safety and efficacy in children has not been established.

Effects on laboratory tests

No data is available.

4.5 Interaction with other medicines and other forms of interactions

Oral medication, especially those medicines with a sustained release, short half-life or a narrow therapeutic window, taken within one hour of the commencing GO-KIT to one hour

after completing its administration, may be flushed from the gastrointestinal tract and not absorbed.

The low-dose contraceptive pill will not work when taken with GO-KIT as it needs as much time as possible in the gastrointestinal tract for absorption.

GO-KIT administration may potentially interact with medicines for heart conditions such as calcium channel blockers, diuretics or other medications that may affect electrolyte levels and other bowel cleansing preparations or laxatives.

GO-KIT administration may potentially interact with medicines for diabetes and diabetic patients may require adjustment of their diabetic medication, as the recommended liquid diet may affect blood glucose levels.

4.6 Fertility, pregnancy and lactation

Effects on fertility

No fertility studies have been conducted.

Use in pregnancy (Category - none)

It is not known whether GO-KIT can cause foetal harm or affect reproductive capacity. GO-KIT should only be used if the benefits clearly outweigh the risks.

Use in lactation

No lactation studies have been conducted.

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)

Nausea, vomiting and anal irritation are the most common reactions. These adverse effects are usually transient and subside rapidly.

Bisacodyl may cause abdominal discomfort such as colic or cramps.

Prolonged use of GO KIT may result in dehydration and electrolyte disturbances (see Section 4.3 and 4.4).

Hypersensitivity reactions including angioedema and anaphylactoid reactions have been reported rarely.

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 <https://www.tga.gov.au/reporting-problems>.

4.9 Overdose

In the event of overdosage, dehydration may occur. Calcium, potassium, chloride and sodium levels should be carefully monitored and immediate corrective action should be taken to restore electrolyte balance with appropriate fluid replacements.

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of action

Bisacodyl

Bisacodyl is a stimulant laxative acting mainly in the large intestine. It acts locally in the gastrointestinal tract, stimulating the sensory nerve endings in the colonic mucosa to produce parasympathetic reflexes resulting in increased peristaltic contractions of the colon. Local axonic reflexes as well as segmental reflexes are initiated in the region of contact and contribute to the widespread peristaltic activity producing evacuation. For this reason, bisacodyl may be used in patients with ganglionic blockage or spinal cord damage (e.g. paraplegia, poliomyelitis). When taken on an empty stomach, bisacodyl tablets will have an effect within six (6) to eight (8) hours. When taken with food the effect of the tablets is exhibited within ten (10) to twelve (12) hours.

Magnesium citrate

Magnesium citrate is an osmotic laxative. It acts by increasing the intestinal osmotic pressure thereby promoting retention of fluid within the bowel. Magnesium citrate draws water from the tissues into the small intestine. This stimulates the normal forward movement of the intestines, peristalsis, resulting in bowel movement within three (3) to six (6) hours.

Clinical trials

No data is available.

5.2 Pharmacokinetic properties

Absorption

Bisacodyl: Absorption from the gastrointestinal tract is minimal with enteric coated tablets or suppositories.

Distribution

No data is available.

Metabolism

Bisacodyl: Following oral administration, bisacodyl is converted to the active desacetyl metabolite bis(p-hydroxyphenyl)pyridyl-2-methane by intestinal and bacterial enzymes.

Excretion

Bisacodyl: The small amount absorbed is excreted in the urine as the glucuronide. Bisacodyl is mainly excreted in the faeces.

5.3 Preclinical safety data

Genotoxicity

No genotoxic studies have been performed.

Carcinogenicity

No carcinogenic studies have been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Bisacodyl

<u>Excipient</u>	<u>Quantity per Tablet (mg)</u>
Antifoam AF Emulsion Q7-2587 (PI 1515)	0.011
Calcium carbonate	3.726
Colloidal anhydrous silica	0.1
Gelatin	0.766
Lactose monohydrate	26.3
Macrogol 6000	0.616
Magnesium stearate	0.4
Maize starch	1.5
Methacrylic acid copolymer	4.513
Microcrystalline cellulose	15.0
Povidone	1.675
Purified talc	10.976
Quinoline yellow	0.02
Sodium starch glycollate type A	4.0
Sucrose	35.396

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 in a dry place. To reduce microbiological hazard, use as soon as practicable after reconstitution. If storage is necessary, the solution may be stored for up to 24 hours in the refrigerator at 2-8°C.

6.5 Nature and contents of container

GO-KIT is presented as a medicine kit packed in an outer carton containing:

- one (1) blister pack of three (3) yellow Bisacodyl 5 mg Tablets and
- one (1) Magnesium Citrate 21.5 g sachet containing a white crystalline powder

The Australian registration number is AUST R 200381.

6.6 Special precautions for disposal

In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 Physicochemical properties

Chemical structure

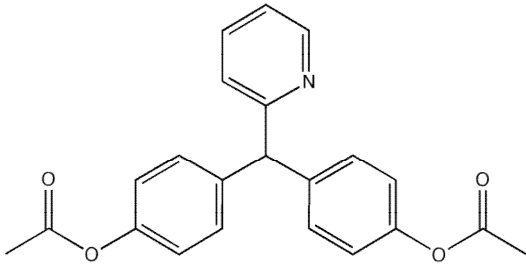
Bisacodyl

The chemical name is 4,4'-(2-pyridylmethylene)di (phenylacetate).

Chemical formula: C₂₂H₁₉NO₄

Molecular weight: 361.4 g/mol

Structural formula:

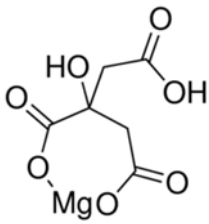


Magnesium citrate

Chemical formula: $C_6H_6MgO_7$

Molecular weight: 214.41 g/mol

Structural formula:

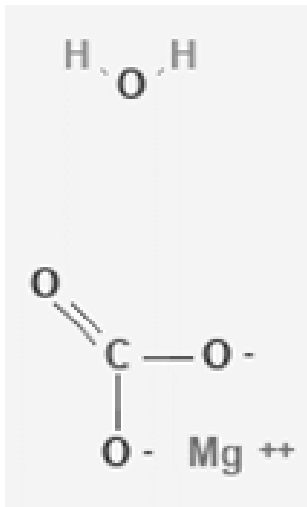


Magnesium carbonate hydrate

Chemical formula: $MgCO_3 \cdot H_2O$

Molecular weight: 84.31 g/mol

Structural formula:

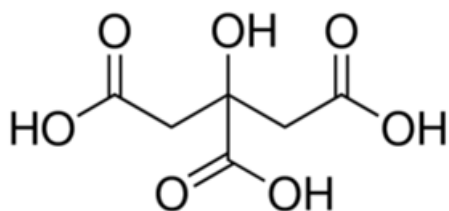


Citric acid

Chemical formula: $C_6H_8O_7$

Molecular weight: 192.1 g/mol

Structural formula:



CAS number

Active Substance

Bisacodyl
Magnesium carbonate hydrate
Citric acid

CAS number

603-50-9
546-93-0
77-92-9

7 MEDICINE SCHEDULE (POISONS STANDARD)

Australia: S3 – Pharmacist Only Medicine

8 SPONSOR

Fresenius Kabi Australia Pty Ltd
Level 2, 2 Woodland Way
Mount Kuring-gai, NSW 2080
Australia.

9 DATE OF FIRST APPROVAL

27 August 2012

10 DATE OF REVISION OF THE TEXT

16 June 2021

Summary table of changes

Section Changed	Summary of new information
All	Reformat PI as per new TGA PI form

APPENDIX I

Recommended Clear Fluids:

- water
- fat-free clear soups (e.g. strained chicken noodle soup)
- broth/bouillon, pulp-free fruit juices (e.g. apple, pear, grape)
- black tea or coffee (no milk)
- electrolyte replacing drinks
- commercial high-energy, fat-free, milk-free nutritional supplements
- carbonated beverages
- clear fruit cordials (lemon, lime, etc.)
- plain jelly
- sorbet
- plain boiled sweets
- gums and jubes

Sugar, salt, and sweetener can be used. No red or purple colouring. Barley sugar may be sucked if required.