COMPOSITION
Macrogol 4000……10.000g per sachet
Excipients with known effect:
Sorbitol (E420) ……1.7 mg per sachet
Sulphur dioxide (E220) ……$0.12x10^{-2}$ mg per sachet

EXCIPIENTS
Saccharin sodium (E954), orange-grapefruit flavour**
**Composition of the orange-grapefruit flavour
Orange and grapefruit essential oils, concentrated orange juice, citral, acetaldehyde, linalol, ethyl butyrate, alpha terpineol, octanal, beta gamma hexenol, maltodextrin, gum arabic, sorbitol, BHA (E320) and sulphur dioxide (E220).

PRODUCT DESCRIPTION
Powder for oral solution in sachet.
Almost white powder with an odour and taste of orange-grapefruit.

PHARMACODYNAMIC PROPERTIES
Pharmacotherapeutic class: OSMOTIC LAXATIVE, ATC code: A06AD15 (A: digestive system and metabolism).

High molecular weight (4000) macrogols are long linear polymers which retain water molecules by means of hydrogen bonds. When administered by the oral route, they lead to an increase in volume of intestinal fluids.

The volume of unabsorbed intestinal fluid accounts for the laxative properties of the solution.

PHARMACOKINETIC PROPERTIES
The pharmacokinetic data confirms that macrogol 4000 undergoes neither gastrointestinal resorption nor biotransformation following oral ingestion.

PRECLINICAL SAFETY DATA
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 or mutagenic effect. Potential drug interactions studies performed in rats on some NSAIDs, anticoagulants, gastric antisecretory agents, or on a hypoglycaemic sulfamide showed that FORLAX did not interfere with gastrointestinal absorption of these compounds. No carcinogenicity studies have been performed.

THERAPEUTIC INDICATIONS
FORLAX® 10g is indicated in symptomatic treatment of constipation in adults and children aged 8 years and above. An organic disorder should have been ruled out before initiation of treatment. FORLAX® 10g should remain a temporary adjuvant treatment to appropriate lifestyle and dietary management of constipation, with a maximum 3- months treatment course in children. If symptoms persist despite associated dietary measures, an underlying cause should be suspected and treated.

POSOLOGY AND METHOD OF ADMINISTRATION
Oral use.
Posology
The dosage is 1 to 2 sachets 10 - 20 g) per day, preferably taken as a single dose in the morning.

The daily dose should be adjusted according to the clinical response and may range from one sachet every other day (especially in children) up to 2 sachets a day.

The effect of FORLAX® 10g becomes apparent within 24 to 48 hours after its administration.

Paediatric Population
In children, treatment should not exceed 3 months due to lack of clinical data for more than 3 months.

forlax® 10g
Macrogol **4000**

Child aged 8 years and above/Adult

Treatment-induced restoration of bowel movements will be maintained by lifestyle and dietary measures.

Method of administration
The content of each sachet should be dissolved in about 50 ml of water just before use and taken in the morning. The resultant solution will be clear and transparent like water.

CONTRAINDICATIONS
- 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,
- Hypersensitivity to the active substance or to any of the excipients.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE
Special Warning
- The treatment of constipation with any medicinal product is only an adjuvant to a healthy lifestyle and diet, for example:
  - increased intake of liquids and dietary fibre,
  - advice on appropriate physical activity and rehabilitation of the bowel reflex.
- An organic disorder should have been excluded before initiation of treatment.
- This medicine contains macrogol (polyethylene glycol). Hypersensitivity (anaphylactic shock, angioedema, urticaria, rash, pruritus, erythema) to drugs containing macrogol (polyethylene glycol) have been reported, see UNDESIRABLE EFFECTS section.
- This medicine contains sulphur dioxide, which may rarely cause severe hypersensitivity reactions and bronchospasm.
- This medicine contains 1.7 mg of sorbitol in each sachet.
- This medicine contains less than 1 mmol sodium (23 mg) per sachet, that is to say essentially "sodium-free".
- In case of diarrhoea, caution should be exercised in patients at risk of disturbances of water-electrolyte balance (e.g. the elderly or patients with impaired hepatic or renal function or patients taken diuretics) and electrolyte control considered.
- Use with caution in patients with impaired gag reflex and patients prone to regurgitation or aspiration. Cases of aspiration have been reported when extensive volumes of polyethylene glycol and electrolytes were administered with nasogastric tube. Neurologically impaired children who have oral-motor dysfunction are particularly at risk of aspiration.
- In patients with swallowing problems, who need the addition of a thickener to solutions to enhance an appropriate intake, interactions should be considered, see INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION section.

Precaution for use

FORLAX® 10g does not contain a significant quantity of sugar or polyol and can be prescribed to diabetic patients or patients on a galactose-free diet.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

There is a possibility that the absorption of other medicinal products could be transiently reduced during use with FORLAX® 10g, particularly medicinal products with a narrow therapeutic index or short half-life such as digoxin, anti-epileptics, coumarins and immunosuppressive agents, leading to decreased efficacy.

FORLAX® 10g may result in a potential interactive effect when used with starch-based food thickeners. The polyethylene glycol (PEG) ingredient counteracts the thickening effect of starch, effectively liquefying preparations that need to remain thick for people with swallowing problems.

PREGNANCY AND LACTATION

Pregnancy

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.

There are limited amount of data (less than 300 pregnancy outcomes) for the use of FORLAX® 10g in pregnant women.

No adverse effects during pregnancy are anticipated since systemic exposure to FORLAX® 10g is negligible. FORLAX® 10g can be used during pregnancy.

Lactation

There are no data on the excretion of FORLAX® 10g in breast milk. No effects on the breast fed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to macrogol 4000 is negligible. FORLAX® 10g can be used during breast feeding.

Fertility

No fertility studies were conducted with FORLAX® 10g. However, since macrogol 4000 is not significantly absorbed, no effect on fertility is anticipated.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

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

UNDESIRABLE EFFECTS

Adverse Drug Reactions are listed under headings of frequency using the following categories:

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).

Adult population:

The undesirable effects listed in the table below have been reported during clinical trials (including 600 adult patients) and post-marketing use. Generally, adverse reactions have been mostly mild and transitory and have mainly concerned the gastrointestinal system:

System Organ Class	Adverse reactions
Gastrointestinal disorders	
Common	Abdominal pain Abdominal distension Diarrhoea* Nausea
Uncommon	Vomiting Defaecation urgency Faecal incontinence
Metabolism and Nutrition Disorders	
Unknown	Electrolytes disorders (Hyponatremia, Hypokalaemia) and/ or dehydration, especially in elderly patients
Immune system disorders	
Unknown	Hypersensitivity (Anaphylactic shock, Angioedema, Urticaria, Rash, Pruritus, Erythema)

Paediatric population:

The undesirable effects listed in the table below have been reported during clinical trials including 147 children aged from 6 months to 15 years and post-marketing use. As in adult population, adverse reactions have generally been mostly mild and transitory and have mainly concerned the gastrointestinal system:

System Organ Class	Adverse reactions
Gastrointestinal disorders	
Common	Abdominal pain Diarrhoea*
Uncommon	Vomiting Abdominal distension Nausea
Immune system disorders	
Unknown	Hypersensitivity (Anaphylactic shock, Angioedema, Urticaria, Rash, Pruritus)

* Diarrhoea may cause perianal soreness

OVERDOSE

Diarrhoea, abdominal pain and vomiting have been reported. In cases of severe diarrhoea, weight loss and electrolytes imbalance may occur. Diarrhoea due to excessive dosing disappears when treatment is temporarily interrupted or the dosage is reduced.

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

STORAGE CONDITIONS

To be stored below 30°C.

Do not exceed the expiry date plainly indicated on the pack. Keep out of reach of children.

(JAUHKAN UBAT DARI KANAK-KANAK)

Further information can be obtained from your doctor or pharmacist.

Pack Size

Box of 10 or 20 sachets.

Product Registration Holder:

Zuellig Pharma Sdn Bhd
No. 15, Persiaran Pasak Bumi, Sek. U8,
Perindustrian Bukit Jelutong
40150, Shah Alam
Malaysia

Manufacturer

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Date of revision

August 2025

7N00510

Cirrus

Approval Signature

Date

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Customer	Mayoly Spindler Laboratories				Colours Used	Fonts Used	Notes
SAP Code	7N00510ID				Keyline (Non-Printing)	Helvetica Neue 8 pt	
SAP Description	NOT M FORLAX 10G 20SACH MY				PANTONE 2376 C	Helvetica Neue (SAP) 7 pt	
Proof / Iteration	2				Technical Info (Non-Printing)	Pluto Cond 9.3 pt	
Artwork Type	Leaflet				Cirrus_Info_Box	Aller 6.3 pt	
Profile Ref	N/A					Din Pro 20.4 pt	
Size	210 x 150 mm						
Specification Ref	N/A						
Barcode Type		Reel Direction	N/A				
Pharmacode	67000510	Copy Position	N/A				
Proof By	ECA	Date	20/08/2025				