APPROVED PROFESSIONAL INFORMATION

SCHEDULING STATUS

S0

1 NAME OF THE MEDICINE

FORLAX Powder for solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains 10 g of macrogol 4 000.

Contains sugar: sorbitol 1,7 mg per sachet.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution in sachet.

A white or almost white powder having a reminiscent odour of orange and grapefruit.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic treatment of chronic functional constipation in adults and children aged 8 years and above.

An organic disorder should have been ruled out before initiation of treatment. FORLAX should remain a temporary adjuvant treatment to appropriate lifestyle and dietary management of constipation, with a maximum 3-month treatment course in children. If symptoms persist despite associated dietary measures, an underlying cause should be suspected and treated.

4.2 Posology and method of administration

Posology

1 to 2 sachets per day, preferably taken as a single dose in the morning.

The effects of FORLAX becomes apparent within 24 to 48 hours after its administration.

In children, treatment should not exceed 3 months due to the lack of clinical data for more than 3 months. Treatment-induced restoration of bowel movements will be maintained by lifestyle and dietary measures.

In adults the need for continuing treatment should be reassessed at 3 months.

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

Method of administration

Oral use.

The content of each sachet should be dissolved in ~~a glass~~ about 50 ml of water just before use. The resultant solution will be clear and transparent like water.

4.3 Contraindications

- Hypersensitivity to macrogol (polyethylene glycol) or to any of the excipients of FORLAX (see section 6.1).
- Severe inflammatory bowel disease (such as ulcerative colitis, Crohn's disease) or toxic megacolon, associated with symptomatic stenosis.
- Digestive perforation or risk of digestive perforation.

- Ileus or suspicion of intestinal obstruction.
- Painful abdominal syndromes of indeterminate cause.

4.4 Special warnings and precautions for use

The treatment of constipation with any medicine is only an adjuvant to a healthy lifestyle and diet, for example:

- increase 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.

FORLAX contains macrogol (polyethylene glycol). Hypersensitivity (anaphylactic shock, angioedema, urticaria, rash, pruritus, erythema) to medicines containing macrogol (polyethylene glycol) have been reported, see section 4.8.

FORLAX contains sulphur dioxide, which may rarely cause severe hypersensitivity reactions and bronchospasm.

Patients with hereditary problems of fructose intolerance should not take FORLAX.

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. 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 section 4.5).

Precautions for use

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

This medicine contains less than 1 mmol sodium (23 mg) per sachet that is to say essentially “sodium- free”.

4.5 Interaction with other medicines and other forms of interaction

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

FORLAX 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.

4.6 Fertility, pregnancy and lactation

Pregnancy

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

reproductive toxicity (see section 5.3).

There is a limited amount of data (less than 300 pregnancy outcomes) for the use of FORLAX in pregnant women.

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

Breastfeeding

There are no data on the excretion of macrogol 4 000 in breast milk. As macrogol 4 000 is not significantly absorbed, FORLAX may be administered during lactation.

Fertility

No fertility studies were conducted with FORLAX however since macrogol 4 000 is not significantly absorbed no effect on fertility is anticipated.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

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

Adverse Drug Reaction Classification Terminology (frequency):

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); unknown (postmarketing data).

Adults:

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:

Children:

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. The adverse reactions have generally been mostly mild and transitory and have mainly concerned the gastrointestinal system:

System organ class	**Children**	**Adults**
Gastrointestinal disorders		
Common	Abdominal pain Diarrhoea*	Abdominal pain Abdominal distension Diarrhoea Nausea
Uncommon	Bloating Vomiting Nausea	Vomiting Defaecation urgency Faecal incontinence
Metabolism and nutrition disorders		
Frequency unknown		Electrolytes disorders (Hyponatraemia, Hypokalaemia) Dehydration
Immune system disorders		
Frequency unknown	Hypersensitivity (Anaphylactic shock, Angioedema,	Hypersensitivity (Anaphylactic shock, Angioedema, Urticaria,

System organ class	Children	Adults
	Urticaria, Rash, Pruritus)	Rash, Pruritus, Erythema)

* Diarrhoea may cause perianal soreness.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8

or Acino Pharma (Pty) Ltd: E-mail: drugsafety_ZA@acino.swiss Tel: 060 998 7896

4.9 Overdose

Excessive doses may cause diarrhoea, generally stops when the dosage is reduced, or treatment temporarily interrupted.

Diarrhoea, abdominal pain and vomiting have been reported. In cases of severe diarrhoea, weight loss and electrolytes imbalance may occur.

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification: A 11.5 Laxatives

Pharmacotherapeutic group: 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.

5.2 Pharmacokinetic properties

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Saccharin sodium (E954), orange-grapefruit flavour**

** Composition of the orange-grapefruit flavour:

Orange and grapefruit oils, concentrated orange juice, citral, acetaldehyde, linalol, ethyl butyrate, alpha terpineol, octanol, beta gamma hexanol, maltodextrin, gum arabic, sorbitol, BHA (E320) and sulphur dioxide (E220).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store at or below 30 ºC.

For single use only. Discard unused solution.

6.5 Nature and contents of container

Single dose white sachets packed in cardboard cartons of 10 or 20. The sachet consists of paper/aluminium/polyethylene layers.

6.6 Special precautions for disposal and other handling

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

Acino Pharma (Pty) Ltd

106 16th Road

Midrand

1686

8 REGISTRATION NUMBER

45/11.5/1129

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23 March 2015

10 DATE OF REVISION OF THE TEXT

16 September 2022