1.3.1.1 PACKAGE INSERT

SCHEDULING STATUS: **S0**

PROPRIETARY NAME (AND DOSAGE FORM):

FORLAX

Powder for solution

COMPOSITION:

Each sachet contains 10 g of macrogol 4000.

Excipients: 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, preservatives: BHA; sulphur dioxide); saccharin sodium.

PHARMACOLOGICAL CLASSIFICATION:

A 11.5 Laxatives

PHARMACOLOGICAL ACTION:

High molecular weight (4000) macrogols are long linear polymers which retain water molecules by means of hydrogen bonds. When adminstered 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.

Pharmacokinetics:

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

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.

CONTRA-INDICATIONS:

- 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.
- Hypersensitivity to macrogol (polyethylene glycol) or to any of the excipients.

WARNINGS AND SPECIAL PRECAUTIONS:

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

- increase intake of liquids and dietary fibre,
- appropriate physical activity and rehabilitation of the bowel reflex.

In case of diarrhoea, caution should be exercised in patients prone to disturbances of water-electrolyte balance (e.g. Patients with impaired hepatic or renal function or patients taking diuretics) and electrolyte control considered.

Special precautions:

Cases of hypersensitivity reactions (rash, urticaria, oedema) have been reported with medicines containing macrogol (polyethylene glycol). Cases of anaphylactic shock have been reported.

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.

Patients with hereditary problems of fructose intolerance should not take this medicinal product.

Effects on ability to drive and use machines:

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

INTERACTIONS:

None known.

PREGNANCY AND LACTATION:

Pregnancy:

Safe use during pregnancy has not been established. There are no adequate data from the use of FORLAX in pregnant women.

Lactation:

There are no data on the excretion of macrogol 4000 in breast milk. As macrogol 4000 is not significantly absorbed, FORLAX may be administered during lactation.

DOSAGE AND DIRECTIONS FOR USE:

Oral use.

1 to 2 sachets per day, preferably taken as a single dose in the morning. Each sachet should be dissolved in a glass of water just before use. For single use only. Discard unused solution.

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.

SIDE EFFECTS:

Adults

Undesirable effects reported during clinical trials involving almost 600 patients with the following frequencies have mainly concerned the gastrointestinal system:

Common (≥ 1/100, < 1/10): abdominal distension and/or pain, nausea, diarrhoea.

Uncommon (≥ 1/1000, < 1/100): vomiting, and the more common consequence of the diarrhoea – urgency to defaecate and faecal incontinence.

Additional information from post-marketing surveillance included cases of hypersensitivity reactions – pruritis, urticaria, rash, face oedema, angioedema and isolated cases of anaphylactic shock have been reported.

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

Children

Undesirable effects have been reported during clinical trials involving 147 children aged from 6 months to 15 years with the following frequencies. The effects concerned the gastrointestinal system:

Gastrointestinal disorders:

Common (≥ 1/100, < 1/10): diarrhoea and abdominal pain.

Uncommon (≥ 1/1000, < 1/100): bloating, vomiting and nausea.

There is no additional information from post-marketing surveillance – hypersensitivity reactions may occur as reported in adults.

Large doses may cause diarrhoea, which may disappears when the dosage is reduced or temporarily interrupted. Diarrhoea may cause perianal soreness.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Overdose leads to diarrhoea which disappears when treatment is temporarily interrupted or the dosage is reduced.

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

Cases of aspiration have been reported when extensive volumes of polyethylene glycol and electrolytes were administered with nasogastric tube. Neurologically impaired children who have oromotor dysfunction are particularly at risk of aspiration.

IDENTIFICATION:

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

PRESENTATION:

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

STORAGE INSTRUCTIONS:

Store at or below 30 ºC. Keep out of the reach of children.

For single use only. Discard unused solution.

REGISTRATION NUMBER:

45/11.5/1129

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE

CERTIFICATE OF REGISTRATION:

Litha Pharma (Pty) Ltd

106, 16th Road

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23 March 2015