1.3.2 PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S0**

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

FORLAX

Powder for solution

Read all of this leaflet carefully because it contains important information for you.

FORLAX is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless you still need to use FORLAX carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share FORLAX with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 3 days

1. WHAT FORLAX CONTAINS

Each sachet contains 10 g of macrogol 4000.

The other ingredients are 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.

2. WHAT FORLAX IS USED FOR

FORLAX is an osmotic laxative used for the treatment of chronic functional constipation in adults and in children from 8 years old.

If symptoms persist despite associated dietary measures, you should contact a doctor.

3. BEFORE YOU TAKE FORLAX

Do not take FORLAX:

- If you are hypersensitive (allergic) to macrogol (polyethylene glycol) or any of the ingredients of FORLAX. (Refer to "WHAT FORLAX CONTAINS", above.)
- If you suffer from severe inflammatory bowel disease (such as ulcerative colitis or Crohn's disease) or an abnormally distended colon (megacolon) associated with symptomatic narrowing of the bowel (stenosis).
- If you have a hole in the wall of the bowel (intestinal perforation) or are at risk of an intestinal perforation.
- If you have impaired bowel passage caused by paralysis of the bowel or a bowel obstruction (ileus) or a suspected bowel (intestinal) obstruction.
- If you are suffering from abdominal pain without knowing the cause.
- If you have a hereditary fructose intolerance.

Take special care with FORLAX:

An organic disorder should have been ruled out before starting 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. In adults the need for continued treatment should be reassessed at 3 months.

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,

- appropriate physical activity and rehabilitation of the bowel reflex.

Cases of allergic reactions involving reddening of the skin, itchy nettle rash and swelling (oedema) have been reported after intake of products containing macrogol (polyethylene glycol). Cases of severe allergic shock reactions (affecting the heart, circulation and/or breathing) have been reported.

In case of diarrhoea, patients with impaired liver or kidney function, patients taking diuretics and elderly patients should contact a doctor, who may consider whether electrolyte control is required.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machinery:

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

Important information about some of the ingredients of FORLAX:

Patients with hereditary fructose intolerance should not take FORLAX.

FORLAX does not contain a significant quantity of sugar or sugar alcohols and is suitable for use by diabetics and patients needing a galactose-free diet.

Taking other medicines with FORLAX:

Always tell your health care professional if you are taking any other medicines.
(This includes complementary or traditional medicines.)

4. HOW TO TAKE FORLAX

Do not share medicines prescribed for you with any other person.

Always take FORLAX exactly as described in this leaflet. You should check with your doctor, pharmacist or other healthcare professional if you are not sure.

Dissolve the contents of each sachet in a glass of water immediately before use and drink the liquid.

Unless otherwise prescribed by your doctor, the usual dose is:

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

For single use only. Discard unused solution.

The daily dose can be adapted according to the effect obtained and may range from one sachet every other day (especially in children) to 2 sachets per day.

The effect of FORLAX becomes apparent 24 to 48 hours after intake.

In children, the duration of treatment with FORLAX should not exceed 3 months.

Treatment-induced restoration of bowel movements should be maintained by a healthy lifestyle and diet (see the relevant information under **'Take special care with FORLAX'**.)

If you have the impression that the effect of FORLAX is too strong or too weak, talk to your doctor, pharmacist or other healthcare professional.

If you take more FORLAX than you should:

This may cause diarrhoea, which disappears when treatment is temporarily interrupted or the dosage reduced.

Excessive fluid loss caused by diarrhoea or vomiting may require correction of electrolyte disturbances and, if this occurs, you should contact a doctor.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center.

If you forget to take FORLAX:

Do not take a double dose to make up for forgotten doses.

5. POSSIBLE SIDE EFFECTS

FORLAX can cause side effects. The following side effects may occur:

If any of the following happen, stop taking FORLAX and tell your doctor immediately or go to the casualty department at your nearest hospital:

Hypersensitivity (allergic) reactions -

- Itching of the skin with compulsive scratching, rash, itching, hives, reddening of the skin, sudden life-threatening allergic reaction (anaphylactic shock).
- Swelling of the hands, feet, ankles, face, lips, mouth, tongue or throat (angioedema) which may cause difficulty in swallowing or breathing.
- Diarrhoea leading to electrolyte disorders (hyponatraemia, hypokalaemia) and/or dehydration, especially in elderly patients.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to FORLAX. You may need urgent medical attention or hospitalisation.

Other side effects that may occur include:

Adults

The side effects have mainly concerned the gastrointestinal tract.

- Frequent: stomach swelling (abdominal distension) and/or pain, nausea, diarrhoea.
- Less frequent: vomiting, and the usual consequences of diarrhoea – urgency to defaecate and faecal incontinence.

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

Children

The side effects have concerned the gastrointestinal tract.

- Frequent: diarrhoea and abdominal pain.
- Large doses may cause diarrhoea which may disappear when the dosage is reduced or treatment temporarily interrupted.
  Diarrhoea may cause soreness around the anus.
- Less frequent: stomach swelling (abdominal distension), vomiting and nausea.

Not all side effects reported for FORLAX are included in this leaflet.
Should your general health worsen while taking FORLAX, please consult your doctor, pharmacist or other healthcare professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF FORLAX

Store all medicines out of reach of children.

Store at or below 30 ºC. For single use only. Discard unused solution.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF FORLAX

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

8. IDENTIFICATION OF FORLAX

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

9. REGISTRATION NUMBER

45/11.5/1129

10. NAME AND ADDRES OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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