PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S0**

FORLAX 10 g Powder for solution

Macrogol 4 000

Contains sugar: 0.0017 g sorbitol/sachet.

Contains sweetner: 0.017 g sodium saccharin/sachet.

Preservatives: Butylated Hydroxyanisole, sulphur dioxide.

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.

What is in this leaflet

1. What FORLAX is and what it is used for
2. What you need to know before you take FORLAX
3. How to take FORLAX
4. Possible side effects
5. How to store FORLAX
6. Contents of the pack and other information

1. What FORLAX is and what it is used for

FORLAX contains the active substance macrogol 4 000 and belongs to a group of medicines called osmotic laxatives. It works by adding water to the stools, which helps to overcome problems caused by very slow bowel movements. FORLAX is not absorbed into the bloodstream or broken down in the body.

FORLAX is used for the treatment of chronic functional constipation in adults and in children aged 8 years and above.

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

2. What you need to know before you take FORLAX

Do not use FORLAX:

- If you are hypersensitive (allergic) to macrogol (polyethylene glycol) or any of the ingredients of FORLAX. (listed in section 6).
- If you have an existing disease, such as, severe intestinal disease:
  - inflammatory bowel disease (such as ulcerative colitis, Crohn's disease, abnormal dilation of the bowel
  - hole in the lining of your colon or risk thereof
  - a temporary lack of the normal muscle contractions of the intestines or suspicion of a blockage that keeps food or liquid from passing through your intestine
  - painful abdominal syndromes of uncertain cause

Warnings and precautions

Take special care with FORLAX.

An organic disorder should have been ruled out before starting treatment.

FORLAX should remain a temporary additional 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 medicine should only be in addition to a healthy lifestyle and diet, for example:

- increased intake of liquids and dietary fibre,
- appropriate physical activity and improvement in the frequency of your bowel movements.

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.

Before taking FORLAX, talk to your doctor or pharmacist if you know that you have a swallowing disorder.

Other medicines and FORLAX

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

It is possible that the absorption of other medicines may temporarily decrease during the use of FORLAX; in particular, it may occur with medicines that have a narrow therapeutic index or a short half-life, such as digoxin, antiepileptic medicines, coumarins, and immunosuppressive medicines, which may reduce their effectiveness. 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.

Pregnancy and breastfeeding

Since absorption of **FORLAX** is negligible, it can be used during pregnancy and breastfeeding.

Driving and using machines

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.

Due to the presence of sulphur dioxide, it may rarely cause severe hypersensitivity reactions and breathing difficulties.

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.

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

3. 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.

Adults and children over 8 years

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

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

Dissolve the contents of each sachet in about 50 ml of water immediately before use and drink the liquid.

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.

Improvement in the frequency of your bowel movements after taking FORLAX can be maintained by keeping to 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

Taking too much FORLAX may cause diarrhoea, stomach pains or vomiting. The diarrhoea usually disappears when treatment is stopped or the dose reduced.

If you suffer from severe diarrhoea or vomiting you should contact a doctor as soon as possible as you may require treatment to prevent loss of salts (electrolytes) from fluid loss.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take FORLAX

Take the next dose as soon as you remember but do not take a double dose to make up for the forgotten individual doses.

4. Possible side effects

FORLAX can have side effects.

Not all side effects reported for FORLAX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FORLAX, please consult your health care provider for advice.

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

Frequency unknown

- 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.

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.

Common

- stomach swelling (abdominal distension) and/or pain,
- nausea,
- diarrhoea.

Uncommon

- vomiting,
- urgency to defaecate,
- faecal incontinence.

Frequency unknown

- low blood levels of potassium which can cause muscle weakness, twitching or abnormal heart rhythm,
- low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits and coma,
- dehydration caused by severe diarrhoea especially in the elderly,
- symptoms of an allergic reaction such as skin redness, rash, hives (urticaria), swelling of the face or throat, breathing difficulties, faintness or collapse.

Children

The side effects have concerned the gastrointestinal tract.

Common

- abdominal pain,
- diarrhoea which may cause soreness around the back passage (anus).

Uncommon

- stomach swelling (abdominal distension),
- vomiting and nausea.

Frequency unknown

- allergic (hypersensitive) reactions (rash, hives (urticaria), swelling of the face or throat, breathing difficulties, faintness or collapse).

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Health care providers are asked to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or to Acino Pharma (Pty) Ltd.: E-mail: drugsafety_ZA@arceralifesciences.com Tel: 060 998 7896

By reporting side effects, you can help provide more information on the safety of FORLAX.

5. How to store 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 or label.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What FORLAX contains

The active substance in each sachet is 10 grams of macrogol 4 000.

The other ingredients are saccharin sodium (E 954) and orange-grapefruit flavour which contains orange and grapefruit essential oils, concentrated orange juice, citral, acetaldehyde, linalol, ethyl butyrate, alpha terpineol, octanal, beta and gamma hexenol, maltodextrin, gum arabic, sorbitol (E 420), BHA (E 320) and sulphur dioxide (E 220).

What FORLAX looks like and contents of the pack

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

FORLAX is available as single dose white sachets packed in cardboard cartons of 10 or 20.

The sachet consists of paper/aluminium/polyethylene layers.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

