

INSTRUCTIONS FOR USE

PLEASE READ THIS LEAFLET CAREFULLY BEFORE TAKING THIS MEDICINE BECAUSE IT CONTAINS IMPORTANT INFORMATION ABOUT THE TREATMENT. IF YOU HAVE ANY QUESTIONS OR ARE NOT SURE ABOUT ANYTHING, YOU SHOULD CONSULT YOUR DOCTOR OR PHARMACIST.

1 What is FORLAX® 10 g?

FORLAX® 10 g is a powder for oral solution. The active ingredient is Macrogol 4000 and the other ingredients are saccharin sodium and orange grapefruit flavour*.

* Orange grapefruit flavour contains orange and grapefruit oils, concentrated orange juice, citral, acetaldehyde, linalol, ethyl butyrate, alpha terpineol, octanal, beta gamma hexanol, maltodextrine, gum arabic, sorbitol(E420), BHA(E320) and sulphur dioxide (E220).

FORLAX® 10 g is available in boxes of 10 or 20 sachets (not all presentations are available locally). Each sachet contains 10 g of Macrogol 4000 as an almost white powder with an odour and taste of orange grapefruit.

2 What is FORLAX® 10 g used for?

FORLAX® 10 g is an osmotic laxative recommended in the symptomatic treatment of constipation in adults and children aged 8 years and above.

This medicine should be used together with appropriate lifestyle and dietary changes which will lessen the symptoms of constipation. These can be discussed with your doctor or pharmacist.

3 How to take FORLAX® 10 g?

Dosage and method of administration

It is recommended to take 1 to 2 sachets per day, preferably in the morning. Each sachet should be dissolved in a glass of water. The effect of FORLAX® 10 g becomes apparent within 24 to 48 hours after its administration.

Duration of treatment

FORLAX® 10 g should not be used as self-medication for more than 2 weeks. If symptoms persist, medical advice should be sought.

BEFORE USING FORLAX® 10 g, please take note of the following:

FORLAX® 10 g should not be taken in the following cases:

- If you are allergic to Macrogols (=P.E.G.=Polyethylene glycol) or to one of the components of FORLAX® 10 g,



Child aged 8 Years and above/Adult

- If you have severe inflammatory bowel disease (such as ulcerative colitis, Crohn’s disease) or toxic megacolon associated with symptomatic stenosis,
- If you have an obstructed bowel or are suffering from stomach pain without knowing the cause,
- Due to the presence of sorbitol in this medicinal product, you should not take FORLAX® if you are suffering from fructose intolerance,
- Due to presence of sulphur dioxide severe allergic reaction is possible but it is very rare.

IF YOU ARE IN DOUBT, YOU SHOULD CONSULT YOUR DOCOTR BEFORE TAKING THIS MEDICINE IN ORDER TO EXCLUDE ALL OTHER ORGANIC REASONS OF CONSTIPATION.

Special warnings

Occasional constipation

FORLAX® 10 g can be helpful in the treatment for occasional short-term constipation. This can often be connected to a recent change in lifestyle. You should seek medical advice if you suffer from constipation that is not related to a change of lifestyle or any constipation with pain, fever, stomach bloating.

Chronic (long term) constipation

Long term constipation is often due to one or two underlying causes:

- Intestinal disease which needs medical treatment,
- An imbalance in the intestinal function due to eating habits and lifestyle.

In this case, the treatment includes increasing daily intake of vegetable-based foodstuffs (green vegetables, wholemeal bread, fruits, an increase in water and fruit juice consumption, an increase in physical activities (sports, walking..) and introduce bowel-training regimen.

FORLAX® 10 g does not contain a significant quantity of sugar or polyol and can be used by a diabetic patient or a patient who is on a galactose free diet.

WHAT OTHER MEDICINE SHOULD BE AVOIDED

FORLAX® 10 g may interfere with the absorption of other drugs if taken simultaneously.

Generally, it is better to take FORLAX® 10 g at least 2 hours apart from other products.

To avoid any possible drug interaction, always inform your doctor or pharmacist if you are taking any other drugs.

4 Possible side effects of FORLAX® 10 g

Like all medicines, FORLAX® 10 g can have side effects. Possible side effects include:

1. Very high dose may cause diarrhoea. In this case, you should discontinue the treatment or reduce the dosage. The symptom of diarrhoea will disappear within 24 to 48 hours of discontinuing treatment. You may resume the treatment with FORLAX® 10 g at a lower dose,
2. In very rare cases, allergic type reactions such as rash, itching and swelling may happen,
3. Other reported side effects are bloating, abdominal pain, nausea, vomiting and borborgym (growling noise in the tummy).

PLEASE INFORM YOUR DOCTOR OR PHARMACIST IF YOU NOTICE ANY SIDE EFFECTS NOT MENTIONED IN THIS LEAFLET.

IF YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE OF FORLAX® 10 g

FORLAX® 10 g may cause diarrhoea if the patient has taken more than the recommended dosage, but the diarrhoea will disappear when the treatment is temporarily interrupted or the dosage is reduced.

PREGNANCY AND BREAST FEEDING

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 outcome) for the use of FORLAX® in pregnant women. Take this medication during pregnancy only after consultation with a doctor. If you discover that you are pregnant during treatment, consult your doctor who will decide on the need to continue treatment.

Breast feeding:

There are no data on the excretion of FORLAX® in breast milk. As Macrogol 4000 is not significantly absorbed, FORLAX® 10 g may be administered during breast feeding.

Fertility:

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

GENERALLY, IT IS ADVISABLE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE DURING PREGNANCY OR BREAST-FEEDING BEFORE TAKING ANY DRUG.

IF YOU FORGET TO TAKE FORLAX® 10 g

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

5 How to store FORLAX® 10 g

Keep FORLAX® 10 g out of reach of children.

You should store FORLAX® 10 g below 25°C. Do not use FORLAX® 10 g after the expiry date printed on the sachet and carton.

6 Who makes FORLAX® 10 g

FORLAX® 10 g manufactured by Beaufour Ipsen Industrie, located at rue Ethe Virton 28100, Dreux, FRANCE.



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