Product Name
FORLAX® 4g, powder for oral solution

Composition
Macrogol 4000 ..... 4.000g per sachet

Excipients with known effect:
Sorbitol (E420) .....0.66 mg per sachet
Sulphur dioxide (E220) .....4.8 x10^{-4} mg per sachet

Excipients
Saccharin sodium (E954), orange-grapefruit flavour**
**Composition of the orange-grapefruit flavour:
Orange and grapefruit essential oils, concentrated orange juice, citral, acetaldehyde, linalol, ethyl butyrate, alpha terpineol, octanal, beta gamma hexenol, maltodextrin, gum arabic, sorbitol, BHA (E320) and sulphur dioxide (E220).

Product Description
Powder for oral solution in sachet.
Almost white powder with an odour and taste of orange grapefruit.

Pharmacodynamic properties
Pharmacotherapeutic class: 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.

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

Preclinical safety data
Toxicological studies in different species of animals did not reveal any signs of systemic or gastrointestinal toxicity of macrogol 4000. Macrogol 4000 had no teratogenic or mutagenic effect. Potential drug interactions studies performed in rats on some NSAIDs, anticoagulants, gastric antisecretory agents, or on a hypoglycaemic sulfamide showed that FORLAX® 4g did not interfere with gastrointestinal absorption of these compounds. No carcinogenicity studies have been performed.

Therapeutic Indications
Symptomatic treatment of constipation in children from 6 months to 8 years.
An organic disorder should have been ruled out by the doctor, especially in the age group under 2 years, before initiation of treatment. FORLAX® 4g should remain temporary adjuvant treatment to appropriate lifestyle and dietary management of constipation, with a maximum 3-months treatment course. If symptoms persist despite associated dietary measures, an underlying cause should be suspected and treated.

Posology and method of administration
Oral route.
Posology
From 6 months to 1 year: 1 sachet (4 g) per day.
From 1 to 4 years: 1 to 2 sachets (4 to 8 g) per day.

forlax® 4g
Macrogol 4000
Child from 6 months to 8 years
kids

From 4 to 8 years: 2 to 4 sachets (8 to 16 g) per day.
The daily dose should be adapted to the clinical effects.
The effect of FORLAX® 4g becomes apparent within 24 to 48 hours after its administration.

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

Method of administration
The contents of each sachet should be dissolved in about 50ml of water just before use and taken in the morning in case of 1 sachet per day, or split among morning and evening in case of more than one sachet per day. The resultant solution will be clear and transparent like water.

Contraindications
- Severe inflammatory bowel disease (such as ulcerative colitis, Crohn's disease), toxic megacolon,
- Digestive perforation or risk of digestive perforation,
- Ileus or suspicion of intestinal obstruction, symptomatic stenosis,
- Painful abdominal syndromes of indeterminate cause,
- Hypersensitivity to the active substance or to any of the excipients.

Special Warnings and Precautions for Use
Special Warnings
- Data on the efficacy in children under the age of 2 years are limited.
- 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,
  - advice on appropriate physical activity and rehabilitation of the bowel reflex.
- An organic disorder should have been excluded before initiation of treatment.
- After a 3-months treatment course, a complete clinical supervision of constipation should be performed.
- This medicine contains macrogol (polyethylene glycol). Hypersensitivity (anaphylactic shock, angioedema, urticaria, rash, pruritus, erythema) to drugs containing macrogol (polyethylene glycol) have been reported, see Undesirable Effects section.
- This medicine contains sulphur dioxide, which may rarely cause severe hypersensitivity reactions and bronchospasm.
- This medicine contains less than 1 mmol sodium (23 mg) per sachet, that is to say essentially "sodium-free".
- This medicine contains 0.66 mg of sorbitol in each sachet.
- In case of diarrhoea, caution should be exercised in patients at risk of disturbances of water-electrolyte

Cirrus

Approval Signature

Date

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balance (e.g. the elderly, 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. Cases of aspiration have been reported when extensive volumes of polyethylene glycol and electrolytes were administered with nasogastric tube. 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 Interaction with Other Medicinal Products and Other Forms of Interaction section.

Precautions for use
FORLAX® 4g does not contain a significant quantity of sugar or polyol and can be prescribed to diabetic children or children on a galactose-free diet.

Interaction with Other Medicinal Products and Other Forms of Interaction
There is a possibility that the absorption of other medicinal products could be transiently reduced during use with FORLAX® 4g, particularly medicinal products with a narrow therapeutic index or short half-life such as digoxin, anti-epileptics, coumarins and immunosuppressive agents, leading to decreased efficacy.
FORLAX® 4g 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 Lactation
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 outcomes) for the use of FORLAX® 4g in pregnant women.
No adverse effects during pregnancy are anticipated since systemic exposure to FORLAX® 4g is negligible.
FORLAX® 4g can be used during pregnancy.

Lactation
There are no data on the excretion of FORLAX® 4g in breast milk.
No effects on the breast fed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to macrogol 4000 is negligible. FORLAX® 4g can be used during breast feeding.

Fertility
No fertility studies were conducted with FORLAX® 4g. However, since macrogol 4000 is not significantly absorbed, no effect on fertility is anticipated.

Effects on Ability to Drive and Use Machines
No studies on the effects on the ability to drive and /or use machines have been performed.

Undesirable Effects
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. Generally, adverse reactions have been mostly mild and transitory and have mainly concerned the gastrointestinal system.
Adverse Drug Reactions are listed under headings of frequency using the following categories:
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 (cannot be estimated from the available data).

System Organ Class	Adverse reactions
Gastrointestinal disorders	
Common	Abdominal pain Diarrhoea*
Uncommon	Vomiting Abdominal distension Nausea
Immune system disorders	
Unknown	Hypersensitivity (anaphylactic shock, angioedema, urticaria, rash, pruritus).

*Diarrhoea may cause perianal soreness.

In adults, the following additional undesirable effects have been observed in clinical trials and post-marketing:
Gastro-intestinal disorders:
Uncommon: Defaecation urgency, faecal incontinence.
Metabolism and nutrition disorders:
Unknown: Electrolytes disorders (hyponatremia, hypokalaemia) and/ or dehydration, especially in elderly patients.
Immune system disorders:
Unknown: Erythema

Overdose
Diarrhoea, abdominal pain and vomiting have been reported. In cases of severe diarrhoea, weight loss and electrolytes imbalance may occur. Diarrhoea due to excessive dosing disappears when treatment is temporarily interrupted or the dosage is reduced. Extensive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances.

Storage Conditions
Store below 30°C in the original package to protect from light.

Pack Size
Box of 10 or 20 sachets. Not all presentations are available locally.

Product Registration Holder
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