

FORLAX[®] POWDER FOR ORAL SOLUTION

Macrogol 4000 (4 g)

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What FORLAX is used for

FORLAX is used for the treatment of constipation in children from 6 months to 8 years and regarded as temporary adjunctive therapy in an appropriate lifestyle and in dietary measures.

How FORLAX works

FORLAX contains the active substance macrogol 4000 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.

Before you use FORLAX

- When you must not use it
 - If your child has
 - severe inflammatory bowel disease (ulcerative colitis, Crohn's disease),
 - toxic mega colon (enlarged large intestine),
 - digestive perforation or risk of perforation,
 - painful abdominal of undetermined reason.
 - a bowel obstruction (Ileus) or suspect of having it
 - If your child is hypersensitive to macrogol or to any of the ingredients in FORLAX.

- Before you start to use it
Always ask your doctor or pharmacist before using this product if you have any doubts.
- Taking other medicines
FORLAX may interfere with the absorption of other medicines if taken simultaneously.

How to use FORLAX

- How much to use
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.
From 4 to 8 years: 2 to 4 sachets (8 to 16 g) per day.

The content of each sachet must be dissolved in about 50 ml of water just before use.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it
Use as directed by your doctor or pharmacist.
- How long to use it
Continue taking FORLAX for the duration that your doctor recommends.

The effect of FORLAX becomes apparent within 1 to 2 days after its administration.

In children, treatment should not exceed 3 months.

- If you forget to use it
Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)
Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too much FORLAX can cause diarrhoea, abdominal pain and vomiting.

While you are using it

- Things you must do
Always take FORLAX exactly as described in this leaflet or as your doctor or pharmacist has told you.
- Things you must not do
 - Do not stop taking the medicine unless advised by your doctor.
 - Do not take any new medicines without consulting your doctor or pharmacist.
 - Do not give this medicine to anyone else, even if they have the same symptoms or condition as you.
- Things to be careful of
 - This medicine contains macrogol (polyethylene glycol). Hypersensitivity (anaphylactic shock, angioedema, urticaria, rash, pruritus, erythema) to drugs containing macrogol have been reported.
 - This medicine contains sulphur dioxide, which may rarely cause severe

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hypersensitivity reactions and breathing difficulties. • This medicine contains sorbitol. The use of FORLAX is not recommended if your child has fructose intolerance. • As this medicine can sometimes cause diarrhoea, check with your doctor or pharmacist before taking this medicine if your child - has impaired liver or kidney function - is taking diuretics (medicines to increase urination) as your child may be at risk of low sodium (salt) or potassium levels in the blood.	- Urgent need to go to the toilet - Fecal incontinence Unknown (frequency cannot be estimated from available data) - 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. - Skin redness Seek medical attention immediately if your child experiences any hypersensitivity reaction.	Almost white powder with an odour and taste of orange grapefruit. - <u>Ingredients</u> • Active ingredient: Macrogol 4000 • Inactive ingredients: Saccharin sodium, orange grapefruit flavour* *Composition: orange and grapefruit essential oils, concentrated orange juice, citral, acetaldehyde, linalol, ethyl butyrate, alpha terpineol, octanal, beta and gamma hexenol, maltodextrin, arabic gum (E414), sorbitol (E420), BHA (E320) and sulphur dioxide (E220). - <u>MAL number</u> MAL21076021X
Side effects Like all medicines, FORLAX can cause side effects, although not everybody gets them	If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.	Manufacturer Mayoly Industrie, 20 Rue Ethe Virton 28100, Dreux, France.
Side effects are usually mild and do not last long and include: Children (from 6 months to 15 years old): Common (may affect up to 1 in 10 people) - Abdominal pain - Diarrhoea* *Diarrhoea may cause soreness of the anus (bottom)	You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)] Storage and disposal of FORLAX - <u>Storage</u> Store below 30°C. Keep out of the reach and sight of children. - <u>Disposal</u> Medicines should not be disposed of via wastewater or household waste. Ask your doctor or pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment. Do not use this medicine after the expiry date stated on the label.	Product Registration Holder Zuellig Pharma Sdn. Bhd. No. 15, Persiaran Pasak Bumi, Seksyen U8, Perindustrian Bukit Jelutong, 40150 Shah Alam, Selangor Darul Ehsan, Malaysia.
Uncommon (may affect up to 1 in 100 people) - Vomiting - Bloating - Nausea	Unknown (frequency cannot be estimated from available data) - Hypersensitivity reactions (itching, rash, hives, swelling of the face or throat, breathing difficulties)	Date of Revision 23/09/2025 Serial Number NPRA (R2) 21/030
Adult: Uncommon (may affect up to 1 in 100 people)	Product Description - <u>What it looks like</u> Powder for oral solution in sachet.	