

FORLAX[®] POWDER FOR ORAL SOLUTION

Macrogol 4000 (10g)

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What FORLAX is used for

FORLAX is used for the treatment of constipation in adults and children aged 8 years above 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 you have
 - 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 you are hypersensitive to macrogol or to any of the ingredients in FORLAX.
 - If you are intolerant to sugar fructose (due to the presence of sorbitol).

- Before you start to use it

Always ask your doctor or pharmacist before using this product if you have any doubts.

If you are pregnant or trying to pregnant or if you are breastfeeding, seek advices from your doctor or pharmacist before taking any medicine.

No effects during pregnancy or breastfeeding are anticipated since systemic exposure to FORLAX is negligible.

FORLAX can be used during pregnancy and breastfeeding.

- Taking other medicines

FORLAX may interfere with the absorption of other medicines if taken simultaneously. Generally, it is better to take FORLAX at least 2 hours apart from other products.

How to use FORLAX

- How much to use

1 to 2 sachets per day.

The content of each sachet must be dissolved in a glass 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.

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Macrogol 4000 (10g)

Things to be careful of

- This medicine contains macrogol (polyethylene glycol).
- This medicine contains sulphur dioxide, which may rarely cause severe hypersensitivity reactions and breathing difficulties.
- As this medicine can sometimes cause diarrhoea, check with your doctor or pharmacist before taking this medicine if:
 - You have impaired liver or kidney function
 - You are taking diuretics (medicines to increase urination) as you may be at risk of low sodium (salt) or potassium levels in the blood.

Side effects

Like all medicines, FORLAX can cause side effects, although not everybody gets them

Side effects are usually mild and do not last long and include:

Adult population:

Common (may affect up to 1 in 10 people):

- Abdominal pain and/or distension
- Diarrhoea
- Nausea

Uncommon (may affect up to 1 in 100 people):

- Vomiting
- Urgent need to go to the toilet
- Fecal incontinence

Unknown (frequency cannot be estimated from the 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

Very rare (may affect up to 1 in 10,000 people):

- Hypersensitivity reactions (itching, rash, hives, swelling of the face or throat, breathing difficulties)

Children:

Common (may affect up to 1 in 10 people):

- Abdominal pain
 - Diarrhoea*
- *Diarrhoea may cause soreness of the anus (bottom)

Uncommon (may affect up to 1 in 100 people):

- Vomiting
- Bloating
- Nausea

Unknown (frequency cannot be estimated from the available data):

- Hypersensitivity reactions

If you experience any hypersensitivity reaction, you should immediately seek medical attention.

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nppra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of FORLAX

Storage

Store below 30°C.

Keep out of the reach and sight of children.

Disposal

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 Description

What it looks like

FORLAX is an almost white powder with an odour and taste of orange grapefruit for oral solution in sachet.

Ingredients

- Active ingredient: Macrogol 4000
- Inactive ingredients: Saccharin sodium, orange grapefruit flavour

MAL number

MAL19986445X

Manufacturer

Mayoly Industrie,
20 Rue Ethe Virton 28100,
Dreux, France.

Product Registration Holder

Zuellig Pharma Sdn. Bhd.
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