

Idrolax[®] 10g Forlax[®] 10g (macrogol 4000)

Your medicine is known by one of the above names, but will be referred to as Idrolax 10g throughout this:

Patient Information Leaflet

Read all of this leaflet carefully because it contains important information for you.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your pharmacist or doctor
- Talk to your pharmacist or doctor if your symptoms worsen or do not improve
- If a side effect occurs and get troublesome, or seems serious to you, or if you experience a side effect not listed in this leaflet, please tell your pharmacist or doctor.

In this leaflet:

- 1) What Idrolax 10g is and what it is used for
- 2) What you need to know before you take Idrolax 10g
- 3) How to take Idrolax 10g
- 4) Possible side effects
- 5) How to store Idrolax 10g
- 6) Contents of the pack and other information

1) What Idrolax 10g is and what it is used for

Idrolax 10g contains the active substance macrogol 4000 and belongs to a group of medicines called osmotic laxatives.

Idrolax 10g carries water to your stool, which loosens and increases stool volume, helping to overcome sluggish bowels.

Idrolax 10g is not absorbed into the bloodstream or broken down in the body.

Idrolax 10g is used for the treatment of constipation in adults and children aged 8 years and over.

Idrolax 10g is a powder that you dissolve in a glass of water (at least 50 ml) and then drink.

Idrolax 10g works gradually within 24 to 48 hours.

The treatment of constipation with any medicine should only be in addition to a healthy lifestyle and diet.

2) What you need to know before you take Idrolax 10g

Do not take Idrolax 10g:

- if you are allergic (hypersensitive) to macrogol (polyethylene glycol) or any of the other ingredients of this medicine (listed in section 6)
- if you have an existing severe intestinal disease such as:
 - inflammatory bowel disease (such as ulcerative colitis, Crohn's disease, abnormal dilation of the bowel)
 - perforation of the bowel or risk of perforation of the bowel
 - ileus or suspicion of intestinal obstruction
 - painful abdominal conditions of unknown cause

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your pharmacist or doctor before taking the medicine.

Warnings and Precautions

Cases of allergic reactions involving rash and swelling of the face or throat (angioedema) have been reported in adults after taking products containing macrogol (polyethylene glycol). Isolated severe allergic reactions have been reported causing faintness, collapse or breathing difficulties and feeling generally unwell. If you experience any of these symptoms you should stop taking Idrolax 10g and seek medical help immediately.

As this medicine can sometimes cause diarrhoea, check with a doctor or pharmacist before taking this medicine if you:

- have impaired liver or kidney function
- are taking diuretics (water tablets) or are elderly as you may be at risk of low sodium (salt) or potassium levels in the blood

Other medicines and Idrolax 10g

Tell your pharmacist or doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Idrolax 10g can be used during pregnancy and breast-feeding. If you are pregnant, or breast-feeding, think you may be pregnant or are planning to have a baby, ask your pharmacist or doctor for advice before taking Idrolax 10g.

Driving and using machines

Idrolax 10g does not affect your ability to drive or use machines.

Important information about some of the ingredients of Idrolax 10g

If you have been told by your doctor that you have an intolerance to some sugars (sorbitol), contact your doctor before taking this medicine. This medicine contains a small amount of a sugar called sorbitol, which is converted to fructose. Idrolax 10g can, however, be used if you are diabetic, or if you are on a galactose-free diet.

3) How to take Idrolax 10g

Always take Idrolax 10g exactly as described in this leaflet or as your pharmacist or doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults and children over 8 years

- The recommended dose is one to two sachets per day, preferably taken as a single dose in the morning
- Start by taking one sachet each day and if needed increase to two sachets each day
- The daily dose can be adjusted according to the effect obtained and may range from one sachet every other day (especially in children) up to a maximum of two sachets per day
- Dissolve the contents of the sachets in a glass of water (at least 50 ml) immediately before use and drink the liquid

Please note:

- Idrolax 10g usually takes 24 to 48 hours to work
- In the management of children with constipation, the duration of treatment with Idrolax 10g should not exceed 3 months
- Improvement in the frequency of your bowel movements after taking Idrolax 10g can be maintained by keeping to a healthy lifestyle and diet

- Talk to your pharmacist or doctor if the symptoms worsen or do not improve

If you take more Idrolax 10g than you should

Taking too much Idrolax 10g 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) due to fluid loss.

If you forget to take Idrolax 10g

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

4) Possible side effects

Like all medicines, Idrolax 10g can cause side effects, although not everybody gets them. The side effects that are usually mild and do not last long include:

In children:

Common (may affect up to 1 in 10 people)

- Abdominal (belly) pain
- Diarrhoea which may also cause soreness around the back passage (anus)

Uncommon (may affect up to 1 in 100 people)

- Nausea (feeling sick) or vomiting
- Abdominal (belly) pain

Not known (frequency cannot be estimated from available data)

- Allergic (hypersensitivity) reactions (rash, hives (urticaria), swelling of the face or throat, breathing difficulties, faintness or collapse)

In adults:

Common (may affect up to 1 in 10 people)

- Abdominal (belly) pain
- Abdominal (belly) bloating
- Nausea (feeling sick)
- Diarrhoea

Uncommon (may affect up to 1 in 100 people)

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

Not known (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
- Symptoms of an allergic reaction such as skin redness, rash, hives (urticaria), swelling of the face or throat, breathing difficulties, faintness or collapse

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects, you can help provide more information on the safety of this medicine.

5) How to store Idrolax 10g

Keep out of the sight and reach of children.

- Do not take Idrolax 10g after the expiry date printed on the carton, or sachet label.
- Idrolax 10g does not require any special storage conditions.
- If the powder becomes discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6) Contents of the pack and other information

What Idrolax 10g contains:

- Each Idrolax 10g 10g sachet contains 10g of macrogol 4000.
- Idrolax 10g 10g also contains saccharin sodium (E954), aroma of orange-grapefruit containing orange and grapefruit oils, concentrated orange juice, citral, acetaldehyde, linalool, ethyl butyrate, alpha terpineol, octanal, beta gamma hexenol, maltedextrine, gum arabic and sorbitol

What Idrolax 10g looks like and contents of the pack

- Idrolax 10g is a white powder with an aroma and taste of orange-grapefruit.
- Idrolax 10g is available in cartons containing 20 sachets.

PL 10383/1303

Idrolax 10g / Forlax 10g

P

Who makes and repackages your medicine?

Your medicine is manufactured by Beaufour Ipsen Industrie, Rue Ethe Virton, 28100 Dreux, France. Procured from within the EU and repackaged by Product Licence Holder: Primecrown Ltd, 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS.

Leaflet date: 19.04.2016

Idrolax 10g® is a registered trademark of Ipsen Pharma S.A.S., France.