

Package leaflet: Information for the user

Laxatev Paediatric 6.9 g Powder for Oral Solution

Read all of this leaflet carefully before you give this medicine to your child 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 doctor or pharmacist.
- This medicine has been prescribed for your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What *Laxatev Paediatric* is and what it is used for
2. What you need to know before you use *Laxatev Paediatric*
3. How to use *Laxatev Paediatric*
4. Possible side effects
5. How to store *Laxatev Paediatric*
6. Contents of the pack and other information

1. What Laxatev Paediatric is and what it is used for

The name of this medicine is *Laxatev Paediatric 6.9 g Powder for Oral Solution*. It is a laxative for the treatment of chronic constipation in children aged 2 to 11 years and for the treatment of very bad constipation (called faecal impaction) in children aged 5 to 11 years.

It helps your child to have a comfortable bowel movement even if your child has been constipated for a long time.

2. What you need to know before you use Laxatev Paediatric

Do not give *Laxatev Paediatric* to your child,

- if your child is allergic to macrogol 3350, sodium chloride, sodium hydrogen carbonate, potassium chloride, or any of the other ingredients of this medicine (listed in section 6)
- if your child has a perforated gut (bowel) wall
- if your child has a blockage in the intestine (gut obstruction, ileus)
- if your child has severe inflammatory bowel disease such as ulcerative colitis, Crohn's disease or toxic megacolon.

Warnings and precautions

Talk to your doctor or pharmacist before giving *Laxatev Paediatric* to your child, if your child has a heart or kidney problem, an impaired gag reflex or reflux oesophagitis (heart-burn caused by back-flow of stomach contents into the oesophagus).

When taking *Laxatev Paediatric* the child should continue to take plenty of fluids. The fluid content of *Laxatev Paediatric* should not replace the regular liquid intake.

Other medicines and *Laxatev Paediatric*

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines.

Some medicines, e.g. anti-epileptics (medicines for epilepsy), may not work as effectively during use with *Laxatev Paediatric*.

When taking large volumes of *Laxatev Paediatric* (e.g. for faecal impaction), your child should not take other medicines within one hour of taking *Laxatev Paediatric*.

Pregnancy and breast-feeding

Laxatev Paediatric can be taken during pregnancy and whilst breast-feeding.

Ask your doctor or pharmacist for advice before giving this medicine.

Driving and using machines

Laxatev Paediatric does not affect the ability to drive or use machines.

***Laxatev Paediatric* contains potassium, sodium and sorbitol**

Laxatev Paediatric contains 0.3 mmol (12 mg) potassium per sachet. This should be taken into consideration if your child takes more than three sachets daily and has reduced kidney function, or if your child is on a controlled potassium diet.

Laxatev Paediatric contains 4.1 mmol (94 mg) sodium per sachet. This should be taken into consideration if your child is on a controlled sodium diet.

The lemon lime flavour in *Laxatev Paediatric* contains sorbitol. If you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before giving this medicinal product.

3. How to use *Laxatev Paediatric*

Always give this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

This medicine can be taken at any time with or without food.

Chronic constipation (constipation for long time):

The dose of *Laxatev Paediatric* depends on the age of the child and their response to treatment.

- As a starting dose, children aged 2 to 6 years should be given 1 sachet each day.
- Children aged 7 to 11 years should be given 2 sachets each day.
- Your doctor may tell you to increase the number of sachets taken until your child has a soft bowel movement. The dose will not usually exceed 4 sachets per day.

It is not necessary to take all of the drink at one time: if the child prefers it, half the drink can be taken in the morning and half in the evening.

Faecal impaction (complete severe constipation):

Before your child takes *Laxatev Paediatric* for faecal impaction, it should be confirmed medically that your child has this condition.

A course of treatment is as follows:

Number of sachets							
Age (years)	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7

5 - 11	4	6	8	10	12	12	12
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The daily number of sachets should be taken one at a time, all consumed within 12 hours (e.g. 8 am to 8 pm). Treatment can be stopped when the medicine has worked. This is shown by the child passing large volumes of stool and/or watery diarrhoea.

Method of administration

- Open the sachet and pour the contents into a glass. Add ¼ glass (about 62.5 ml) of water to the glass. Stir well until all the powder has dissolved and the solution is clear or slightly hazy, then give it to your child to drink.
- If your child is taking *Laxatev Paediatric* for faecal impaction it may be easier to dissolve 12 sachets in 750 ml of water and to administer the solution evenly spread over a 12 hour period. Reconstituted *Laxatev Paediatric* solution should be covered and stored in the refrigerator (2°C to 8°C).

Duration of treatment

- Chronic constipation: Treatment needs to be for a prolonged period of time, at least 6 to 12 months.
- Faecal impaction: Treatment can be for up to 7 days.

If your child takes more *Laxatev Paediatric* than they should

Your child may develop excessive diarrhoea, which can lead to dehydration. If this occurs, your child should stop taking *Laxatev Paediatric* and drink plenty of fluids. If you are worried contact your doctor or pharmacist.

If you forget to give *Laxatev Paediatric*

If you forget to give a dose, give it as soon as you remember and then continue on as before. Do not give a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If your child experiences any of the following side effects, tell your doctor immediately and stop giving *Laxatev Paediatric* to your child:

- signs of an allergic reaction, such as shortness of breath or difficulty in breathing, swelling of the face, lips, tongue or throat, nettle rash, itching, skin rash or reddening of the skin.
- signs of a change in your child's fluid or electrolyte levels, such as swelling (mainly in the ankles), feeling weak, increasingly tired or increased thirst with headache.

Very common side effects (may affect more than 1 in 10 people):

- stomach pains
- stomach rumbles.

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

- diarrhoea. If your child is being treated for chronic constipation, diarrhoea will usually improve when the dose is reduced
- vomiting (being sick)
- nausea (feeling sick)
- anal discomfort (uncomfortable sensation around the bottom).

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

- swollen stomach
- wind.

Rare side effects (may affect up to 1 in 1,000 people):

- allergic reactions, which may include breathlessness or difficulty in breathing

Frequency not known (frequency cannot be estimated from the available data):

- swelling of the face, lips or throat
- skin rash (hives), itching, reddening of the skin or a nettle rash
- swollen hands, feet or ankles
- headaches
- indigestion
- high or low levels of potassium in the blood.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store *Laxatev Paediatric*

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and sachet. The expiry date refers to the last day of that month.

Do not use this medicine if you notice that any of the sachets is damaged.

Do not store above 25°C.

If reconstituted *Laxatev Paediatric* solution cannot be taken straight away, it should be covered and stored in the refrigerator (2°C to 8°C), and should be used within 24 hours. After 24 hours, any unused solution should be discarded.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information**What *Laxatev Paediatric* contains**

The active substances are:

macrogol 3350	6.563 g
sodium chloride	175.4 mg
sodium hydrogen carbonate	89.3 mg
potassium chloride	23.3 mg

The other ingredients are silica colloidal anhydrous, saccharin sodium, orange flavour (Orange flavour contains: flavouring preparations and substances, natural flavouring substances, maltodextrin, acacia, α -tocopherol) and lemon lime flavour (Lemon lime flavour contains: natural lemon oil, natural powder flavour lemon, powder flavour lime, maltodextrin, mannitol, gluconolactone, sorbitol, acacia, silica colloidal anhydrous).

What *Laxatev Paediatric* looks like and contents of the pack

Laxatev Paediatric is a white powder.

Each sachet contains 6.9 g of powder and is packed in cartons containing 30 and 50 sachets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Teva Pharma B.V.
Swensweg 5
2031GA Haarlem
The Netherlands

Manufacturer

Merckle GmbH
Ludwig-Merckle-Straße 3
89143 Blaubeuren
Germany

Teva Pharma B.V.
Swensweg 5
2031 Haarlem
The Netherlands

Klocke Pharma-Service GmbH:
Straßburger Straße 77
77767 Appenweiler
Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

United Kingdom Macilax Paediatric 6.9 g Powder for Oral Solution

Belgium Curapeg Junior 6,9 g voor drank

Germany Macrogol-ratiopharm Junior 6,9 g Pulver zur Herstellung einer Lösung zum Einnehmen

Ireland Laxatev Paediatric 6.9 g Powder for Oral Solution

This leaflet was last revised in August 2017.