



Juniorlax[®]

6,9 g powder for preparing an oral solution

Active substances: Macrogol 3350, sodium chlorid, sodium hydrogen carbonate, potassium chlorid

Read all of this leaflet carefully before your child start taking this medicine because it contains important information for you.

Make sure that your child always takes this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

Keep this leaflet. You may need to read it again.

- Ask your pharmacist if you need more information or advice.
- If your child gets any side effects even though you observe such side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

1. What Juniorlax[®] is and what it is used for
2. What you or your child needs to know before you take Juniorlax[®]
3. How to take Juniorlax[®]
4. Possible side effects
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6. Contents of the pack and other information

1. What Juniorlax[®] is and what it is used for

Juniorlax[®] is a laxative.

Juniorlax[®] is used for the treatment of chronic constipation in children aged 2 to 11 years.

2. What you or your child needs to know before you take Juniorlax[®]

Do not use Juniorlax[®]

- if your child is allergic (hypersensitive) to the active substances or any of the other ingredients of this medicine (listed in section 6)
- if a blockage of the intestine or a bowel obstruction exist.
- if the risk of a bowel rupture exists
- if a severe inflammatory bowel disease exist (ulcerative colitis, Crohn's disease, toxic megacolon)

Warnings and precautions

Symptoms in adults while taking medicinal products containing macrogol have been rarely reported, which indicates a shift in the fluid and electrolyte balance, e.g. oedema, respiratory distress, increasing tiredness, lack of water (dehydration), heart failure. If these side effects occur, taking Juniorlax[®] has to be stopped immediately and a doctor has to be contacted.

Juniorlax[®] contains 0.3 mmol (12.2 mg) of potassium per sachet. This should be taken into consideration if your child takes more than one sachet daily and has reduced kidney function, or if it is on a controlled potassium diet.

Juniorlax[®] contains 4.1 mmol (93.8 mg) of sodium per sachet. This should be taken into consideration if your child is on a controlled sodium diet.

Pregnancy and breast-feeding

Juniorlax[®] can be taken during pregnancy and whilst breast-feeding.

Other medicines and Juniorlax[®]

Please tell your doctor or your pharmacist if your child takes, has recently taken or might take any other medicines. The efficacy of some medicinal products, e.g. anti-epileptics, concomitantly administered with Juniorlax[®] can be decreased.

Juniorlax[®] with food and drink

This medicinal product can be taken at any time with food or drink.

Juniorlax[®] contains sorbitol

If you are aware that your child has an intolerance to some sugars, please contact your doctor before taking Juniorlax[®].

3. How to take Juniorlax[®]

Always give this medicine to your child exactly as described in this leaflet, respectively, exactly as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Unless otherwise prescribed by your doctor, the usual dose is:

At the beginning of treatment, children aged 2 to 6 years usually take the content of one sachet as the daily dose, children aged between 7 to 11 years take the contents of 2 sachets. During the further course of treatment, the daily dose should be increased or reduced as necessary in order to ensure a regular bowel movement with a soft consistency of the faeces.

An increase in dose, if required, this should take place every second day. Normally, the maximum required daily dose should not exceed more than 4 sachets.

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

If the child has very soft stools or diarrhea, the dose should be reduced to one sachet (if 2 or more sachets have been taken per day) or a daily dose should be omitted (if only one sachet has been taken per day).

Method of administration

For preparing a ready-for-use oral solution each sachet should be dissolved in 62.5 ml (quarter of a glass) of water. Stir well until all the powder has dissolved and the Juniorlax[®] solution is clear or slightly hazy, then give it to your child to drink.

The daily dose (total amount of solution) can be prepared in advance, sealed and stored in a refrigerator for a period of up to 24 hours.

Please consult your doctor or pharmacist if you have the impression that the efficacy of Juniorlax[®] being too strong or too weak.

Duration of treatment

The treatment of children with chronic constipation should be carried out over a longer period of time (at least 6 to 12 months).

If your child takes more Juniorlax[®], than it should

Contact your doctor if severe pains, swelling of the abdomen, or severe diarrhea occurs.

If your child forgets to take Juniorlax[®]

Do not take a double dose at the same time. Taking has to be continued as described in this package leaflet.

If your child stops taking Juniorlax[®]

Do not stop or discontinue treatment of your child without consultation with your doctor or pharmacist.

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

4. Possible side effects

Like all medicines, Juniorlax® can cause side effects, although not everybody gets them.

If one of the mentioned side effects severely impairs your child, or if you notice that your child experiences side effects that are not mentioned in the package leaflet, then please inform your doctor or pharmacist.

Inform your doctor immediately and stop taking Juniorlax® if your child shows signs of a serious allergic reaction, such as difficulty in breathing, or swelling of the face, lips, tongue or throat.

The following categories are used as a basis when evaluating the frequency of side-effects:

Very common

(may affect more than 1 in 10 people):

- Stomach pain
- Stomach rumbles

Common

(may affect up to 1 in 10 people)

- Diarrhea
- Vomiting
- Nausea
- Discomfort in the anal area
(unpleasant feeling in the anus)

If your child is being treated for chronic constipation, diarrhoea will usually improve when the dose is reduced.

Uncommon

(may affect up to 1 in 100 people):

- Bloating belli
- Bloating

Very rare

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

- Allergic reactions which cause shortness of breath or difficulties in breathing.

Further side effects that have been reported include: Rash, itching, reddening of the skin or a nettle rash, swelling of the hands, feet or ankle, headache, digestive disorders, irritation in the anal areas, changes in body's electrolyte levels (potassium levels in the blood are higher or lower than normal)

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 Federal Institute for Drugs and Medical Devices, Dept. of Pharmacovigilance, Kurt-Georg-Kiesinger Allee 3, D-53175 Bonn, Website: <http://www.bfarm.de>. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Juniorlax®

Keep out of the reach and site 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.

Once you have made up Juniorlax® in water, if your child cannot drink it straight away keep the ready-to-use oral solution sealed and store it by room temperature (below 25 °C) for a maximum of 3 hours or in a refrigerator (2 °C – 8 °C) for a maximum of 24 hours.

Throw away any solution not used within a 24 hour period. 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 Juniorlax® contains

One sachet Juniorlax® contains the following active substances:

Macrogol 3350 (polyethylene glycol 3350)	6.563 g
Sodium chloride	0.1754 g
Sodium hydrogen carbonate	0.0893 g
Potassium chloride	0.0233 g

After dissolving the contents of a sachet (6.9 g) in 62.5 ml water (1/4 glass), a ready-to-use solution is obtained with the following content of electrolytes:

Sodium	65 mmol/l
Chloride	53 mmol/l
Hydrogen carbonate	17 mmol/l
Potassium	5 mmol/l

The other ingredients are:

Highly dispersed silicon dioxide, Saccharin-sodium, Orange aroma (orange aroma contains: flavouring and aromatic extracts, maltodextrin, gum Arabic, alpha-tocopherol), Lemon-lime aroma (lemon-lime aroma contains: aromatic extracts, maltodextrin, mannitol (E 421), D-glucono-1,5-lactone, sorbitol (E 420), gum Arabic, highly dispersed silicon dioxide).

What Juniorlax® looks like and content of the pack

Juniorlax® is a white powder.

Each sachet contains 6.9 g powder and is available in boxes of 6, 8, 10, 20, 30, 40, 50, 60 or 100 sachets. Not all pack sizes may be marketed.

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This leaflet was last revised in 2017.

Dear Patient!

It is possible that the leaflet in your medicine pack may differ from this version.

This leaflet is an internal, unofficial translation of the German package leaflet and may not apply to other countries.