

Package leaflet: Information for the user

Abdomin Junior Neutral powder for oral solution in sachets

macrogol 3350, sodium chloride, sodium hydrogen carbonate, potassium chloride

RX

Read all of this leaflet carefully before you start to 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, pharmacist or nurse.
- This medicine has been prescribed for your child. 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 get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

OTC

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

Always give this medicine to your child exactly as described in this leaflet or as your doctor, pharmacist or nurse have 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 get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if your child do not feel better or if your child feel worse.

What is in this leaflet

1. What [Invented name] is and what it is used for
2. What you need to know before you give [Invented name]
3. How to give [Invented name]
4. Possible side effects
5. How to store [Invented name]
6. Contents of the pack and other information

1. What [Invented name] is and what it is used for

The name of this medicine is [Invented name]. It is a laxative for the treatment of chronic constipation in children aged 1 to 11 years and for the treatment of very bad constipation (called faecal impaction) in children aged 5 to 11 years.

[Invented name] helps your child to have a comfortable bowel movement even if they have been constipated for a long time.

2. What you need to know before you give [Invented name]

Do not give [Invented name] if your doctor has told you that your child has:

- an allergy to macrogol 3350, sodium chloride, sodium hydrogen carbonate, potassium chloride or any of the other ingredients of this medicine (listed in section 6)
- a blockage in their intestine (gut obstruction, ileus)
- a perforated gut wall
- severe inflammatory bowel disease like ulcerative colitis, Crohn's disease or toxic megacolon.

Warnings and precautions

When taking [Invented name] you should continue to take plenty of fluids. The fluid content of [Invented name] should not replace your regular liquid intake.

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), you should talk to your doctor before giving [Invented name].

Other medicines and [Invented name]

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, may not work as effectively during use with [Invented name].

When taking large volumes of [Invented name] (e.g. for faecal impaction), other medicines may be flushed through your digestive system. Your child should not take any other medicines by mouth together with [Invented name] and for one hour before and for one hour after taking [Invented name].

If you need to thicken fluids in order to swallow them safely, [Invented name] may counteract the effect of the thickener.

Pregnancy and breast-feeding

[Invented name] can be given during pregnancy and whilst breastfeeding. Ask your pharmacist or doctor for advice before giving [Invented name].

Driving and using machines

[Invented name] has no effect on the ability to drive or use machines.

[Invented name] contains potassium and sodium

This medicine contains 12.2 mg potassium per sachet. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

This medicine contains 93 mg (4.06 mmol) sodium (main component of cooking/table salt) per sachet. This is equivalent to 4.7% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to give [Invented name]

RX

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

OTC

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

Dissolve the content of each sachet in 62.5 ml (1/4 of a glass) of water and drink.

Chronic Constipation:

The dose of [Invented name] depends on the age of the child and their response to treatment.

- As a starting dose, children aged 1 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. If the dose does need increasing, this should be done every other day. For children below 2 years of age, no more than 2 sachets should be taken in one day. For children 2 to 11 years, normally, no more than 4 sachets are required to be taken in one 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:

Before your child takes [Invented name] for faecal impaction, it should be confirmed medically that your child has this condition.

A course of treatment for faecal impaction in children aged 5 to 11 years is as follows:

Number of [Invented name] 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

The daily number of sachets should be taken in divided doses, all consumed within 12 hours (e.g. 8am to 8pm). Each sachet dissolved in 62.5 ml (1/4 of a glass) of water. Treatment can be stopped when the medicine has worked. This is shown by the child passing large volumes of stool and/or watery diarrhoea.

How to mix

- Open the sachet and pour the contents into a glass. Add about 62.5 ml or ¼ glass of water to the glass. Stir well until all the powder has dissolved and the [Invented name] solution is clear or slightly hazy, then give it to your child to drink.
- If you like you can add a flavour such as orange squash to the drink. If your child is taking [Invented name] for faecal impaction it may be easier to dissolve 12 sachets in 750 ml of water.

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

Duration of treatment

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

If your child takes more [Invented name] than they should

Your child may develop excessive diarrhoea. If this occurs, stop taking [Invented name] and drink plenty of fluids. If you are worried contact your doctor or pharmacist.

If you forget to give [Invented name]

Give the dose as soon as you remember.

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

4. Possible side effects

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

Tell your doctor immediately and stop giving [Invented name] if your child:

- gets a serious allergic reaction which causes difficulty in breathing or swelling of the face, lips, tongue or throat.

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
- vomiting (being sick)
- nausea (feeling sick)
- anal discomfort (uncomfortable sensation around the bottom).

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

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.

Other side effects reported include:

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 [the national reporting system listed in Appendix V](#). By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store [Invented name]

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.

This medicine does not require any special storage conditions.

Once you have made up [Invented name] in water, if your child cannot drink it straight away keep it covered and in the fridge (2 - 8°C). 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 [Invented name] contains**

- The active substances are macrogol 3350 (6.563 g), sodium chloride (175.4 mg), sodium hydrogen carbonate (89.3 mg) and potassium chloride (23.3 mg).
- The other ingredient is colloidal anhydrous silica.

See section 2 [Invented name] contains potassium and sodium.

[Invented name] contains no colours, flavours or sweeteners.

When it is made into a drink with 62.5 ml ($\frac{1}{4}$ glass) of water, each sachet gives the equivalent of:

Sodium	65 mmol/l
Chloride	53 mmol/l
Hydrogen carbonate	17 mmol/l
Potassium	5.4 mmol/l

What [Invented name] looks like and contents of the pack

[Invented name] is a white, chrystalline powder packed in sachets.

It is available in boxes of 6, 8, 10, 20, 30, 40, 50, 60, 100 or 100 (2x50) sachets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the European Economic Area under the following names:

[To be completed nationally]

This leaflet was last revised in <{MM/YYYY}>

[To be completed nationally]

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