
Package leaflet: Information for the patient

Movicol Junior Neutral 6.9g sachet, powder for oral solution

Macrogol 3350, Sodium Chloride, Sodium Hydrogen Carbonate, Potassium Chloride

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 gets any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Movicol Junior Neutral is and what it is used for

The name of this medicine is Movicol Junior Neutral 6.9g sachet, powder for oral solution. 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.

Movicol Junior Neutral 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 Movicol Junior Neutral

Do not give Movicol Junior Neutral if your doctor has told you that your child has:

- 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
- an allergy to the active substances of Movicol Junior Neutral (listed in section 6).

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 Movicol Junior Neutral.

Warnings and precautions

When taking Movicol Junior Neutral you should continue to take plenty of fluids. The fluid content of Movicol should not replace your regular liquid intake.

Other medicines and Movicol Junior Neutral

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

Some medicines, e.g. anti-epileptics, may not work as effectively during use with Movicol Junior Neutral. When taking large volumes of Movicol Junior Neutral (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 Movicol Junior Neutral and for one hour before and for one hour after taking Movicol Junior Neutral.

If you need to thicken fluids in order to swallow them safely, Movicol Junior Neutral may counteract the effect of the thickener.

Pregnancy and breast feeding

Movicol Junior Neutral can be given during pregnancy and whilst breastfeeding. Ask your pharmacist or doctor for advice before giving Movicol Junior Neutral.

Movicol Junior Neutral contains sodium

Movicol Junior Neutral contains 93.4 mg sodium (main component of cooking/table salt) per sachet. This is equivalent to 4.6% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to give Movicol Junior Neutral

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

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

Chronic Constipation:

The dose of Movicol Junior Neutral 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 (=1 dose) each day.
- Children aged 7 to 11 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 Movicol Junior Neutral for faecal impaction, it should be confirmed medically that your child has this condition.

A course of treatment with Movicol Junior Neutral is as follows:

	Number of Movicol Junior Neutral 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 taken within 12 hours (e.g. 8am – 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 your 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 Movicol Junior Neutral 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 Movicol Junior Neutral for faecal impaction it may be easier to dissolve 12 sachets in 750ml of water.

Duration of treatment

Chronic constipation:

Treatment needs to be for a prolonged period of time, at least 6 – 12 months.

Faecal impaction:

Treatment with Movicol Junior Neutral can be for up to 7 days.

If your child takes more Movicol Junior Neutral than they should:

Your child may develop excessive diarrhoea. If this occurs, stop taking Movicol Junior Neutral and drink plenty of fluids. If you are worried contact your doctor or pharmacist.

If you forget to give Movicol Junior Neutral:

Give the dose as soon as you remember.

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 Movicol Junior Neutral 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 (more than 1 person in 10)

- stomach pains
- stomach rumbles

Common side effects (more than 1 in 100 but less than 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 (more than 1 in 1000 but less than 1 in 100 people)

- swollen stomach
- wind

Rare side effects (less than 1 person in 1000)

- 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 your child gets 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 Movicol Junior Neutral

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

- Do not use Movicol Junior Neutral after the expiry date which is stated on the sachet and carton. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions.
- Once you have made up Movicol Junior Neutral in water, if your child cannot drink it straight away keep it covered and in the fridge (2°C – 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 Movicol Junior Neutral contains

Each 6.9g sachet of Movicol Junior Neutral contains the following:

Macrogol 3350	6.563 g
Sodium Chloride	0.1754 g
Sodium Hydrogen Carbonate	0.0893 g
Potassium Chloride	0.0251 g

Movicol Junior Neutral contains no colours, flavours or sweeteners.

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

Sodium	65 millimoles/litre
Chloride	53 millimoles/litre
Potassium	5.4 millimoles/litre
Bicarbonate	17 millimoles/litre

What Movicol Junior Neutral looks like and contents of the pack

Movicol Junior Neutral is available in rectangular sachet and tubular (stick-pack) sachet.

Movicol Junior Neutral is a white powder.

Movicol Junior Neutral is available in boxes of 6, 8, 10, 20, 30, 40, 50, 60 or 100 sachets. Not all sachets and pack sizes may be marketed.

Marketing authorisation holder:

[To be completed nationally]

Manufacturer:

Norgine B.V., Antonio Vivaldistraat 150, 1083 HP Amsterdam, The Netherlands.

Or

Meribel Pharma Höganäs AB, Sporthallsvägen 6, 263 35 Höganäs, Sweden.

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

Austria	MOVICOL Junior aromafrei
Belgium	MOVICOL Junior Neutral
Finland	MOVICOL Junior Plain
Germany	Macrogol Norgine Junior Neutral Pulver zur Herstellung einer Lösung zum Einnehmen
Ireland	MOVICOL Paediatric Plain
Italy	MOVICOL Bambini 6,9 g polvere per soluzione orale, Senza Aroma
Luxembourg	MOVICOL Junior Neutral
Malta	MOVICOL Paediatric Plain
Portugal	Movicol Pediátrico Sabor Neutro
Spain	MOVICOL Pediátrico Sabor Neutro
Sweden	Movicol Junior Neutral

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