

Package leaflet: information for the patient
MOVICOL Paediatric Plain 6.9 g sachet, powder for oral solution

Read all of this leaflet carefully before starting to give this medicine to your child as it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you to.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If your child experiences any side effects, including those not listed on this leaflet, please contact your doctor, pharmacist or nurse. See section 4.
- Should you not notice any improvement or notice a worsening of your symptoms, please contact your doctor.

What is in this leaflet

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

1. What is Movicol Paediatric Plain and what it is used for

The name of this medicine is Movicol Paediatric Plain 6.9g sachet, powder for oral solution. It is a laxative for treating chronic constipation in children aged 1 to 11 years and for treating severe constipation (called faecoloma) in children aged 5 to 11 years.

Movicol Paediatric Plain helps your child to have a comfortable bowel movement even if constipation has persisted over an extended period of time.

2. What you need to know before you give Movicol Paediatric Plain

Do not give Movicol Paediatric Plain if the doctor advised you that your child has:

- a blockage of the intestine (intestinal obstruction, Ileus)
- a perforated gut wall
- a severe inflammatory bowel disease such as ulcerative colitis, Crohn's disease or toxic megacolon
- an allergy to the active substances of Movicol Paediatric Plain (listed in section 6)

If your child has heart problems or kidney problems, an impaired gag reflex or reflux esophagitis (heart-burn caused by back-flow of stomach contents into the oesophagus), seek and consult your doctor before taking Movicol Paediatric Plain.

Warnings and precautions

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

Other medicines and Movicol Paediatric Plain

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

Some medicines (e.g. anticonvulsants) may not work as effectively while taking Movicol Paediatric Plain. When taking large volumes of Movicol Paediatric Plain (e.g. in cases of faecoloma), your child should not take any other medication within one hour of taking Movicol Paediatric Plain.

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

Pregnancy and breastfeeding

Movicol Paediatric Plain can be taken during pregnancy and whilst breastfeeding. Consult your pharmacist or doctor before giving Movicol Paediatric Plain.

Movicol Paediatric Plain contains sodium

Movicol Paediatric Plain flavour contains 93.4 mg (4.062 mmol) of sodium (main component of table salt) per sachet. This is equivalent to 4.6% of the maximum recommended daily dietary intake for an adult.

3. How to give Movicol Paediatric Plain

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 Paediatric Plain depends on the age of the child and 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 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 it is necessary to increase dosage, this should be done every other day. Children aged under 2 years should be given no more than 2 sachets per day. For children aged between 2 and 11 years, normally no more than 4 sachets per day are required.

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.

Faecaloma

Before your child takes Movicol Paediatric Plain for the treatment of faecaloma, it should be confirmed medically that your child has this condition.

A course of treatment with Movicol Paediatric Plain is as follows:

Number of Movicol Paediatric Plain 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 over a 12-hour period (e.g. 8:00am - 8:00pm). Each sachet should be 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 its contents into a glass. Add 1/4 glass of water (around 62.5 ml). Stir well until all the powder has dissolved and the Movicol Paediatric Plain solution is clear or slightly hazy, then give it to your child to drink.
- If preferred, you can alter the taste of the drink, for example by adding orange juice. If your child is taking Movicol Paediatric Plain for faecaloma, it may be easier to dissolve 12 sachets in 750 ml of water.

Duration of treatment Chronic constipation:

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

Faecaloma

Treatment with Movicol Paediatric Plain can be up to 7 days.

If your child takes more Movicol Paediatric Plain than they should:

It may cause excessive diarrhoea, which can lead to dehydration. If this occurs, stop taking Movicol Paediatric Plain and drink plenty of fluids. If you are worried contact your doctor or pharmacist.

If you forget to give Movicol Paediatric Plain

Give the dose as soon as you remember.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not all people experience them.

Contact your doctor immediately and stop giving Movicol Paediatric Plain if your child:

- gets a severe allergic reaction that causes difficulty breathing, or swelling of the face, lips, tongue or throat.

Very common side effect (more than 1 in 10 people):

- 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 treated for chronic constipation, diarrhoea normally improves by reducing the dose.

Uncommon side effects (more than 1 in 1000 by less than 1 in 100 people):

- swollen stomach
- flatulence

Rare side effects (less than 1 in 1000):

- allergic reactions which may include shortness of breath or difficulty in breathing

Other reported side effect include:

skin rashes, itching of the skin or hives, swelling of the hands, feet or ankles, headaches, poor digestion, high or low potassium levels 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 through the national reporting system at <https://www.aifa.gov.it/content/segnalazioni-reazioni-avverse>

Reporting undesirable effects may help provide more information on the safety of this medicine.

5. How to store Movicol Paediatric Plain

Keep this medicine out of sight and reach of children.

- Do not use Movicol Paediatric Plain after the expiry date which is stated on the sachet and on the box.
- The expiry dates refers to the last day of that month.

- This medicine does not require any special storage conditions.
- Once you have made up Movicol Paediatric Plain in water, if your child cannot drink it all at once, store in the fridge (2°C - 8°C / 35°F - 46°F) and keep it covered. Throw away the unused solution within 24 hours.

Do not dispose of any medicines in waste water or household waste. Ask your pharmacist how to dispose of the medicines you no longer take/use. These measures will help protect the environment.

6. Contents of the pack and other information What Movicol Paediatric Plain contains

Each 6.9 g sachet of Movicol Paediatric Plain contains the following:

Macrogol 3350	6.563 g
Sodium Chloride	0.1754 g
Sodium hydrogrogen carbonate	0.0893 g
Potassium Chloride	0.0251 g

Movicol Paediatric Plain contains no colours, flavours, or sweeteners.

When dissolved in a quarter glass of water (62.5 ml), each sachets provides the equivalent of:

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

Description of what Movicol Paediatric Plain looks like and contents of the packet

Movicol Paediatric Plain is a white powder.

Movicol Paediatric Plain is available in boxes of 6, 8, 10, 20, 30, 40, 50, 60 or 100 sachets.

Not all packs may be marketed.

Marketing authorisation holder:

Norgine Italia S.r.l., Via Fabio Filzi 25, 20124 Milano Italy

Manufacturer responsible for batch release:

Norgine Limited, New Road, Hengoed, Mid Glamorgan, CF82 8SJ (United Kingdom)

or

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

or

Recipharm Höganäs AB, Sporthallsvägen 6, Höganäs, 263 35, Sweden

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

Austria	MOVICOL Junior aromafrei
Belgium	Movicol Junior Neutral
Denmark	Movicol Junior Neutral
Finland	MOVICOL Junior Plain
Germany	Macrogol Norgine Junior Neutral Pulver zur Herstellung einer Lösung zum Einnehmen
Iceland	Movicol Junior Neutral
Ireland	MOVICOL Paediatric Plain
Italy	Movicol Bambini 6,9 g polvere per soluzione orale Senza Aroma

Luxembourg
Malta
The Netherlands
Norway
Portugal
Spain
Sweden
United Kingdom

Movicol Junior Neutral
MOVICOL Paediatric Plain
Movicolon Junior Naturel
MOVICOL Junior
MOVICOL Pediátrico Sabor Neutro
MOVICOL Pediátrico Sabor Neutro
Movicol Junior Neutral
MOVICOL Paediatric Plain

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Sales dealer:

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