

## Package leaflet: Information for the patient

# MOVICOL<sup>®</sup> Paediatric Plain 6.9g sachet, powder for oral solution

**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 Paediatric Plain is 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 Movicol Paediatric Plain is 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 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.

MOVICOL Paediatric Plain 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 Paediatric Plain

**Do not give Movicol Paediatric Plain 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 Paediatric Plain (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 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. anti-epileptics, may not work as effectively during use with Movicol Paediatric Plain. When taking large volumes of Movicol Paediatric Plain (e.g. for faecal impaction), your child should not take other medicines within one hour of taking Movicol Paediatric Plain.

#### Pregnancy and breast feeding

Movicol Paediatric Plain can be given during pregnancy and whilst breast feeding. Ask your pharmacist or doctor for advice before giving Movicol Paediatric Plain.

### 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 62.5ml (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 their response to treatment.

- As a starting dose, children aged 2 to 6 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. 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 Paediatric Plain for faecal impaction, it should be confirmed medically that your child has this condition.

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

Age (years)	Number of Movicol Paediatric Plain sachets						
	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 62.5ml or 1/4 glass of water to the glass. 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 you like you can add a flavour such as orange squash to the drink. If your child is taking Movicol Paediatric Plain 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 to 12 months.

##### Faecal impaction:

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

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

Your child may develop excessive diarrhoea. 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 everybody gets them.

#### Tell your doctor immediately and stop giving Movicol Paediatric Plain 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 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 Movicol Paediatric Plain**

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

- Do not use Movicol Paediatric Plain after the expiry date which is stated on the sachet and carton.
- The expiry date refers to the last day of that month.
- Do not store your Movicol Paediatric Plain above 25° C.
- Once you have made up Movicol Paediatric Plain 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 Paediatric Plain contains**

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

Macrogol 3350	6.563 g
Sodium chloride	0.1754 g
Sodium bicarbonate	0.0893 g
Potassium chloride	0.0251 g

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

When it is made into a drink with ¼ glass (62.5ml) of water, each sachet gives the equivalent of:

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

**What Movicol Paediatric Plain looks like and contents of the pack**

Movicol Paediatric Plain 6.9g sachet, powder for oral solution is available in pack sizes of 30 sachets, contained in an overlabeled outer carton.

**Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder:**

PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath

**Manufacturer:**

Norgine Ltd, New Road, Hengoed, Mid Glamorgan, CF82 8SJ, UK.

**Parallel Product Authorisation Number:** PPA 465/159/2

Movicol is a registered trademark of VELINOR AG.

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

Austria	MOVICOL Junior aromafrei
Germany	MOVICOL Junior aromafrei
Belgium	MOVICOL Junior Neutral
Sweden	MOVICOL Junior Neutral
Finland	MOVICOL Junior Plain
UK	MOVICOL Paediatric Plain
Ireland	MOVICOL Paediatric Plain
Italy	MOVICOL Bambini 6,9 g polvere per soluzione orale Senza Aroma
Spain	MOVICOL Pediátrico Sabor Neutro
Netherlands	Movicolon Junior Naturel
Luxembourg	MOVICOL Junior Neutral
Denmark	MOVICOL Junior Neutral
Norway	MOVICOL Junior
Switzerland	MOVICOL Paediatric Plain

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