



## PACKAGE LEAFLET

### Package leaflet: Information for the patient

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

#### **1. What Movicol Paediatric Chocolate flavour is and what it is used for**

The name of this medicine is Movicol Paediatric Chocolate flavour 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 Chocolate flavour 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 Chocolate flavour**

**Do not give Movicol Paediatric Chocolate flavour 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 or any of the other ingredients of Movicol Paediatric Chocolate flavour (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 Chocolate flavour.



### **Warnings and precautions**

When taking Movicol Paediatric Chocolate flavour 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 Chocolate flavour**

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 Chocolate flavour.

When taking large volumes of Movicol Paediatric Chocolate flavour (e.g. for faecal impaction), your child should not take other medicines within one hour of taking Movicol Paediatric Chocolate flavour.

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

### **Pregnancy and breast feeding**

Movicol Paediatric Chocolate flavour can be given during pregnancy and whilst breastfeeding. Ask your pharmacist or doctor for advice before giving Movicol Paediatric Chocolate flavour.

### **MOVICOL Paediatric Chocolate contains benzyl alcohol**

MOVICOL Paediatric Chocolate contains 7.0 mg of benzyl alcohol per sachet. Benzyl alcohol may cause allergic reactions.

Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist.

Ask your doctor or pharmacist for advice if your child has a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in the body and may cause side effects (called “metabolic acidosis”).

MOVICOL Paediatric Chocolate 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 Paediatric Chocolate flavour**

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 Chocolate flavour depends on the age of the child and their response to treatment.

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

A course of treatment with Movicol Paediatric Chocolate flavour is as follows:

	<b>Number of Movicol Paediatric Chocolate flavour sachets</b>						
<b>Age (years)</b>	<b>Day 1</b>	<b>Day 2</b>	<b>Day 3</b>	<b>Day 4</b>	<b>Day 5</b>	<b>Day 6</b>	<b>Day 7</b>
<b>5-11</b>	<b>4</b>	<b>6</b>	<b>8</b>	<b>10</b>	<b>12</b>	<b>12</b>	<b>12</b>

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 ¼ glass (about 62.5ml) of water to the glass. Stir well until all the powder has dissolved and the Movicol Paediatric Chocolate flavour 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 Chocolate flavour 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 Paediatric Chocolate flavour can be for up to 7 days.

**If your child takes more Movicol Paediatric Chocolate flavour than they should:**

Your child may develop excessive diarrhoea, which can lead to dehydration. If this occurs, stop taking Movicol Paediatric Chocolate flavour and drink plenty of fluids. If you are worried contact your doctor or pharmacist.

**If you forget to give Movicol Paediatric Chocolate flavour:**

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 Chocolate flavour 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 Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store Movicol Paediatric Chocolate flavour**

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

- Do not use Movicol Paediatric Chocolate flavour 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 Paediatric Chocolate flavour 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 Chocolate flavour contains

Each 6.9g sachet of Movicol Paediatric Chocolate flavour powder for oral solution contains the following:

Macrogol 3350	6.563 g
Sodium Chloride	0.1754 g
Sodium Hydrogen Carbonate	0.0893 g
Potassium Chloride	0.0159 g

Movicol Paediatric Chocolate flavour contains chocolate flavour (which includes benzyl alcohol E1519, see section 2 “MOVICOL Paediatric Chocolate contains benzyl alcohol”) and acesulfame potassium E950 as a sweetener.

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	51 millimoles/litre
Potassium	5.4 millimoles/litre
Bicarbonate	17 millimoles/litre

### **What Movicol Paediatric Chocolate flavour looks like and contents of the pack**

Movicol Paediatric Chocolate flavour is a white to light brown powder.

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

Not all pack sizes may be marketed.

### **Marketing authorisation holder:**

Norgine BV, Antonio Vivaldistraat 150, 1083 HP Amsterdam, Netherlands.

### **Manufacturer:**

Norgine Limited, New Road, Hengoed, Mid Glamorgan, CF82 8SJ, U.K.

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 EEA under the following names**

<b>Belgium</b>	MOVICOL Junior Aroma /MOVICOL Junior Arôme
<b>Germany</b>	Macrogol Norgine Junior Schokoladengeschmack
<b>Finland</b>	Movicol Junior Chocolate
<b>Ireland</b>	Movicol Paediatric Chocolate flavour
<b>Italy</b>	MOVICOL Bambini 6,9 g polvere per soluzione orale gusto Cioccolato
<b>Luxembourg</b>	MOVICOL Junior Arôme
<b>Netherlands</b>	Movicolon Junior Chocolate
<b>Portugal</b>	Movicol Pediátrico Chocolate
<b>Spain</b>	MOVICOL Pediátrico Sabor Chocolate
<b>Sweden</b>	Movicol Junior Choklad
<b>United Kingdom</b>	Movicol Paediatric Chocolate flavour

**This leaflet was last revised in 11/2021**

**Other sources of information**

If you need the information on this leaflet in an alternative format, such as large print, please ring 00 44 1895 826 606.