

Package leaflet: Information for the user

Movilief Paediatric 6.9g Powder for Oral Solution, Sachet

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for your child only. 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Movilief Paediatric is and what it is used for
2. What you need to know before you give Movilief Paediatric
3. How to give Movilief Paediatric
4. Possible side effects
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1. What Movilief Paediatric is and what it is used for

The name of this medicine is Movilief Paediatric powder for oral solution.

- It is a laxative for the treatment of chronic constipation and for the treatment of very bad constipation (called faecal impaction) in children aged 2 to 11 years.
- It helps your child to have a comfortable bowel movement even if they have been constipated for a long time.
- It also helps prevent very bad constipation re-occurring after successful treatment in children aged 2 to 11 years.

2. What you need to know before you give Movilief Paediatric

DO NOT give Movilief Paediatric if your doctor has told you that your child has:

- an allergy to any of the ingredients of this medicine (listed in section 6)
- a blockage in their intestine (gut obstruction, ileus) for example by paralysis of the intestine
- a perforated gut wall
- severe inflammatory bowel disease like ulcerative colitis, Crohn's disease or toxic megacolon

If any of these apply to your child, please talk to your doctor or pharmacist for further advice.

Warnings and precautions

If your child develops side effects such as swelling, shortness of breath, feeling tired, dehydration (symptoms include increasing thirst, dry mouth and weakness) or heart problems you should stop giving Movilief Paediatric and contact your doctor immediately.

Diagnosis of faecal impaction/faecal loading of the rectum should be confirmed by the physical or radiological examination of the abdomen and rectum.

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 Movilief Paediatric.

Other medicines and Movilief Paediatric

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 effectively during use with Movilief Paediatric. Tell your doctor about any other medicines your child is taking. When taking large volumes of

Movilief Paediatric (e.g. for faecal impaction), your child should not take other medicines within one hour of taking Movilief Paediatric.

Pregnancy and breast-feeding

If your child is pregnant or breast feeding talk to your doctor before giving Movilief Paediatric.

Driving and using machines

Movilief Paediatric has no effect on the ability to drive or use machines.

Movilief Paediatric contains 0.34mmol (13mg) of potassium per sachet. This should be taken into consideration if your child takes more than one sachet daily and has reduced kidney function, or is on a controlled potassium diet.

Movilief Paediatric contains 4.065mmol (93.5mg) of sodium per sachet. This should be taken into consideration if your child is on a controlled sodium diet.

3. How to give Movilief Paediatric

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

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

Chronic Constipation (Constipation for a long time):

The dose of Movilief Paediatric 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 each day.
- Children aged 7 to 11 years should be given 2 sachets each day.
- The dose should be adjusted up or down as required to produce regular soft stools. If the dose needs to be increased this is best done every second day. The maximum dose needed does not normally exceed 4 sachets a day.

Treatment of children with chronic constipation needs to be for a prolonged period (at least 6 - 12 months). However, safety and efficacy have only been proved for a period of up to three months. Treatment should be stopped gradually and resumed if constipation recurs.

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 (Complete severe constipation):

Before your child takes Movilief Paediatric for faecal impaction, it should be confirmed medically that your child has this condition.

A course of treatment for faecal impaction in children aged **2 to 4 years** is as follows:

Day 1	-	2 sachets	Day 5	-	6 sachets
Day 2	-	4 sachets	Day 6	-	8 sachets
Day 3	-	4 sachets	Day 7	-	8 sachets
Day 4	-	6 sachets			

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

Day 1	-	4 sachets	Day 5	-	12 sachets
Day 2	-	6 sachets	Day 6	-	12 sachets
Day 3	-	8 sachets	Day 7	-	12 sachets
Day 4	-	10 sachets			

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

Method of Administration

- 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 solution is clear or slightly hazy, then give it to your child to drink.
- If your child is taking Movilief Paediatric 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. However, safety and efficacy have only been proved for a period of up to three months. Treatment should not be stopped at once, but gradually and resumed if constipation recurs.
- Faecal impaction: Treatment can be up to 7 days.

Children (below 2 years of age):

This product is not recommended for children below 2 years of age.

Patients with renal insufficiency or a heart condition

This product is not recommended for children with renal insufficiency or a heart condition, since there is no experience with these kinds of patients.

If your child takes more Movilief Paediatric than they should

Your child may develop excessive diarrhoea, which can lead to dehydration. If this occurs, stop giving Movilief Paediatric and give your child plenty of fluids. If you are worried contact your doctor or pharmacist.

If you forget to give Movilief Paediatric

Give the dose as soon as you remember and then continue as before. Do not give a double dose to make up for a forgotten dose.

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

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 Movilief Paediatric if your child:

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

Very common (may affect more than 1 in 10 people)

- stomach pains
- stomach rumbles (borborygmi)

Common (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 (may affect up to 1 in 100 people)

- swollen stomach
- wind

Rare (may affect up to 1 in 1,000 people)

- allergic reactions, which may include breathlessness or difficulty in breathing

Not known (frequency cannot be estimated from the available data)

- 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
- Peri-anal inflammation

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 Movielief Paediatric

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 after 'EXP'. The expiry date refers to the last day of that month.

Unopened sachet: No special storage conditions.

Once you have made up Movielief Paediatric 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 Movielief Paediatric contains

The active substances are macrogol 3350 (6.563g), sodium chloride (175.4mg), sodium hydrogen carbonate (89.3mg) and potassium chloride (23.3mg).

The other ingredients are lemon flavour and acesulfame potassium (E950) as a sweetener. The lemon flavour contains the following ingredients: acacia gum (E414) and flavouring.

What Movielief Paediatric looks like and contents of the pack

Movielief Paediatric is a white powder packed in sachets. It is available in boxes of 10, 20, 30, 40, 60, 80, 90, 100, 120, 140, 150, 160, 180 or 200 sachets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder is:

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

The manufacturer is:

Chanelle Medical, Loughrea, Co. Galway, Ireland

STADA Arzneimittel AG, Stadastrasse 2–18, 61118 Bad Vilbel, Germany

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Centrafarm Services B.V., Nieuwe Donk 9, NL-4879 AC Etten-Leur, The Netherlands

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

Belgium: Macrogol + Electrolytes Junior EG 6,9g poeder voor drank

Germany: Macrogol STADA 6,9g Pulver zur Herstellung einer Lösung zum Einnehmen

Ireland: Movilief Paediatric 6.9g powder for oral solution
Luxembourg: Macrogol + Electrolytes Junior EG 6,9g poudre pour solution buvable
Netherlands: Macrogol en electrolyten CF 6,9 g, poeder voor drank

This leaflet was last revised in May 2014.