Patient Information Leaflet

MOVICOL® Junior Chocolate Flavour

Please read this leaflet carefully before taking your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

What is this medicine?

The name of this medicine is Movicol Junior Chocolate Flavour. Each sachet contains:

Macrogol 3350 6.563 g
Sodium chloride 175.4 mg
Sodium bicarbonate 89.3 mg
Potassium chloride 15.9 mg

When it is made into a drink with 62.5 mL of water, each sachet gives the equivalent of:

Sodium 65 mmol/L
Chloride 51 mmol/L
Bicarbonate 17 mmol/L
Potassium 5.4 mmol/L

Movicol Junior Chocolate also contains chocolate flavour and acesulfame potassium as a sweetener The chocolate flavour includes maltodextrin, acacia gum, vegetable oils and fats, propylene glycol, benzyl alcohol, and sulfites.

Each sachet contains 6.9 grams of Movicol Junior Chocolate powder. You add the water to the powder to make a drink.

What is Movicol Junior Chocolate used for?

MOVICOL Junior Chocolate is used in children aged 2 years and older and adults for the treatment of chronic constipation. Constipation is the "less frequent than normal" passing of firm or hard stools. MOVICOL Junior Chocolate helps you to have a comfortable bowel movement even if you have been constipated for a long time.

Chronic Constipation in Children:

Most normal children will occasionally experience constipation, which will normally require no more than a healthy diet, plenty of exercise, regular toilet use and, sometimes, occasional use of laxatives.

However, a small proportion of children will pass stools less frequently than 3 times per week, with excessive straining and discomfort or pain at these times. If your child has this more severe type of constipation your doctor needs to be involved in making a supervised plan of treatment for your child over the next 6 –12 months. Treatments may require daily use of a product such as Movicol Junior Chocolate which can keep stools of normal consistency and restore a normal pattern of passing stools.

Movicol Junior Chocolate is also used in children aged 2 years and older for the treatment of faecal impaction (as determined by your doctor), and for the prevention of recurrence of faecal impaction.

Before you take Movicol Junior Chocolate

Do not take Movicol Junior Chocolate if your doctor has told you that you have:

- an obstruction in your intestine (gut)
- a perforated gut wall
- severe inflammatory bowel disease, like ulcerative colitis, Crohn's disease, or toxic megacolon
- paralysis of the bowel
- an allergy to macrogol or any of the ingredients

Pregnancy and breast feeding

If you are pregnant, talk to your doctor before you take MOVICOL Junior Chocolate. Movicol Junior Chocolate can be taken whilst breast feeding.

Other Medicines

Laxative products such as Movicol Junior Chocolate have the potential to interact with other medications, by altering their absorption. Close monitoring of the effects of your medications may be necessary when you start or stop taking MOVICOL Junior Chocolate regularly. It is important that you should discuss this with your doctor.

How to take Movicol Junior Chocolate

Chronic Constipation/Prevention of recurrence of faecal impaction:

Children aged 2-5 years: The usual starting dose is 1 sachet daily.

Children aged 6-11 years: The usual starting dose is 2 sachets daily. The dose should be adjusted up or down as required to produce regular soft stools. The maximum dose needed does not normally exceed 4 sachets daily.

Use in children aged 2 years and older should be limited to 12 weeks except under medical supervision. Movicol Junior Chocolate is not recommended for children below 2 years of age. *Adults and children 12 years and older:* The recommended dose of MOVICOL Junior Chocolate is 2 sachets a day. This can be increased up to 6 sachets daily if necessary, depending on the severity of your constipation. For chronic constipation the dose may be reduced to 1 sachet daily, according to individual response.

For patients 12 years and older using 2 sachets daily or more, it is recommended to use Movicol Chocolate.

FAECAL IMPACTION:

Children (2 – 11 years):

A course of treatment with Movicol Junior Chocolate is for up to 7 days as follows:

| | Number of MOVICOL Junior Chocolate Sachets | | | | | | |
|-------------|--|-------|-------|-------|-------|-------|-------|
| Age (years) | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | Day 6 | Day 7 |
| 2 - 5 | 2 | 4 | 4 | 6 | 6 | 8 | 8 |
| 6 - 11 | 4 | 6 | 8 | 10 | 12 | 12 | 12 |

Treatment can be stopped when the medicine has worked. This is shown by the patient passing large volumes of stool or watery diarrhoea. Movicol Junior Chocolate is not recommended for the treatment of faecal impaction in children with a heart or kidney condition.

Do not use Movicol Junior Chocolate to treat faecal impaction in children for longer than 7 days. If symptoms persist, see your doctor.

If you take too much Movicol Junior Chocolate and get bad diarrhoea, stop taking Movicol Junior Chocolate until the diarrhoea stops. If constipation returns, you should check with your doctor or pharmacist. If you are worried, contact your doctor or pharmacist.

General Recommendations when taking Laxatives

Drink plenty of water. Increase fibre in diet, except in cases of medication-induced constipation. Prolonged use of laxatives is undesirable and may lead to dependence. In some circumstances, prolonged use may be necessary but should only be under medical supervision.

How to Prepare Movicol Junior Chocolate

Open the sachet and pour contents into a glass. Add 62.5 mL (about ¼ cup) of water into the glass. Stir well until all the powder has dissolved and the Movicol Junior Chocolate solution is clear or slightly hazy, then drink it.

For use in faecal impaction, the correct number of sachets can be made up in advance and kept covered and refrigerated for 24 hours. For example 12 sachets can be made up into 750 mL of water and 16 sachets into one litre of water.

What about side effects?

Like all medicines, Movicol Junior Chocolate can have side effects. Sometimes people have indigestion, stomach ache or rumbles. You may also feel bloated, suffer from wind, feel sick or vomit, may also experience soreness of the anus (bottom) and may have mild diarrhoea when starting to take Movicol Junior Chocolate. Diarrhoea generally gets better if you reduce the amount of Movicol Junior Chocolate you take. If necessary, discuss reducing the dose with your doctor or pharmacist. Other side effects include allergic reactions which may cause a skin rash, itching, reddening of the skin or a nettle rash. Tell your doctor or pharmacist if you think Movicol Junior Chocolate is causing you any problem.

Tell your doctor immediately and stop taking Movicol Junior Chocolate if you:

- Get a serious allergic reaction which causes difficulty in breathing, or swelling of the face, lips, tongue or throat.
- If you feel weak, breathless, very thirsty with a headache, or get puffy ankles.

How to store Movicol Junior Chocolate Storing Movicol Junior Chocolate sachets

Store the sachets below 30°C. Do not use Movicol Junior Chocolate after the expiry date on the pack.

Storing prepared solution of Movicol Junior Chocolate

If you do not drink it straightaway, the prepared Movicol Chocolate solution can be kept covered in the fridge (2-8°C) for up to 24 hours. After that time, any remaining solution should be thrown away.

Keep out of reach of children.

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