

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

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PROPRIETARY NAME AND DOSAGE FORM

MOVICOL CHOCOLATE

Powder for Reconstitution

Read all of this leaflet carefully because it contains important information for you

MOVICOL CHOCOLATE is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use MOVICOL CHOCOLATE carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share MOVICOL CHOCOLATE with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

WHAT MOVICOL CHOCOLATE CONTAINS

Each 13,9 g sachet of MOVICOL CHOCOLATE contains:

13,125 g of macrogol 3350

350,7 mg sodium chloride

178,5 mg sodium bicarbonate

31,7 mg potassium chloride

When MOVICOL CHOCOLATE is made into a drink with 125 ml of water each sachet gives

the equivalent of:

sodium 65 mmol/l

chloride 51 mmol/l

potassium 5,4 mmol/l

bicarbonate 17 mmol/l

The other ingredients are:

Acesulfame potassium, chocolate flavour (containing maltodextrin, acacia gum, vegetable oils and fats, propylene glycol, ethyl alcohol).

Contains sweetener: Acesulfame potassium 0,05 g

Sugar free

WHAT MOVICOL CHOCOLATE IS USED FOR

MOVICOL CHOCOLATE is a laxative for the treatment of constipation in adults, adolescents and elderly. It is not recommended for children below 12 years of age.

MOVICOL CHOCOLATE helps you to have a bowel movement.

BEFORE YOU TAKE MOVICOL CHOCOLATE

Do not take MOVICOL CHOCOLATE

- If you are hypersensitive (allergic) to macrogol, sodium chloride, sodium bicarbonate, potassium chloride or any of the other ingredients of MOVICOL CHOCOLATE.

Do not take MOVICOL CHOCOLATE if your doctor has told you that you have

- A blockage in your intestine (gut obstruction, ileus)
- A perforated gut wall

- Severe inflammatory bowel disease like ulcerative colitis, Crohn's disease or toxic megacolon
- An allergy to any of the ingredients
- Ileus

Take special care with MOVICOL CHOCOLATE

- If you have stomach ache, feel nauseous or are vomiting.
- Consult your doctor before using MOVICOL CHOCOLATE if you notice a sudden change in your bowel habits that persists for a period longer than 2 weeks.
- Consult your doctor if you experience rectal bleeding or do not have a bowel movement after using MOVICOL CHOCOLATE.
- Do not use MOVICOL CHOCOLATE frequently or for long periods as this may cause dependence and a loss of normal bowel function.

Taking MOVICOL CHOCOLATE with food and drink

MOVICOL CHOCOLATE can be taken at any time with or without food or drink.

It is recommended to take MOVICOL CHOCOLATE before a meal.

Pregnancy and breastfeeding

Always tell your healthcare provider if you are taking any other medicine. If you are pregnant or breastfeeding your baby, please consult your healthcare provider before taking MOVICOL CHOCOLATE.

Taking other medicines with MOVICOL CHOCOLATE

Always tell your healthcare provider if you are taking any other medicines (This includes complementary or traditional medicines).

HOW TO TAKE MOVICOL CHOCOLATE

Always take MOVICOL CHOCOLATE exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Do not share medicines prescribed for you with any other person.

A dose of MOVICOL CHOCOLATE is 1 sachet. Take this 1 to 3 times a day according to the severity of your constipation. The dose may be adjusted up or down, according to how hard or soft your stool is.

When MOVICOL CHOCOLATE is first started, it may take a few days to start working.

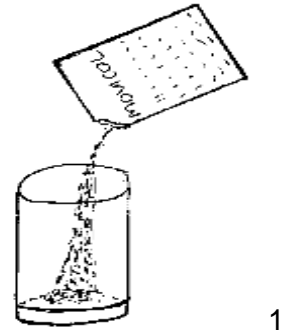
Adults: 1 sachet 1 to 3 times a day. For extended use, 1 or 2 sachets a day.

Elderly: Initially, 1 sachet a day.

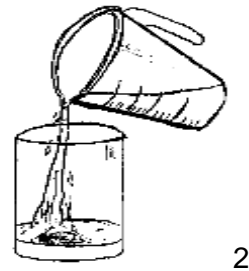
If you have the impression that the effect of MOVICOL CHOCOLATE is too strong or too weak, talk to your doctor or pharmacist.

Instructions for use:

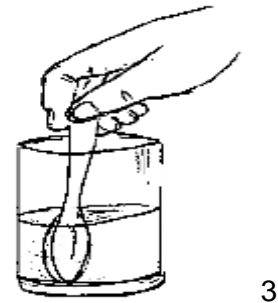
1. Open one sachet and pour the contents of one sachet of MOVICOL CHOCOLATE into a glass.



2. Add 125 ml ($\frac{1}{2}$ glass) of water.



3. Stir the mixture well until all the powder has dissolved and the MOVICOL CHOCOLATE solution is clear or slightly hazy.



4. Drink the solution.

Duration of treatment

Treatment with MOVICOL CHOCOLATE usually lasts for about 2 weeks.

If your constipation is caused by an illness such as Parkinson's disease or multiple sclerosis (MS), or if you take medicines that cause constipation your doctor may recommend that you take MOVICOL CHOCOLATE for longer than 2 weeks.

If you take more MOVICOL CHOCOLATE than you should

You may develop diarrhoea. Stop taking MOVICOL CHOCOLATE until the diarrhoea clears,

and then start again at a lower dose. In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take MOVICOL CHOCOLATE

Take the dose as soon as you remember to take it.

Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS

MOVICOL CHOCOLATE can have side effects.

Not all side effects reported for MOVICOL CHOCOLATE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MOVICOL CHOCOLATE, please consult your healthcare provider for advice.

Tell your doctor immediately and stop taking MOVICOL CHOCOLATE if:

- You feel weak, increasingly tired, breathless, very thirsty with a headache or get puffy ankles.
- You have a skin rash or itching which may be signs of an allergic reaction. Other possible signs of an allergic reaction include difficulty in breathing or dizziness.

Other side effects that you may have include:

Less frequent

- Stomach pain or diarrhoea but this will usually improve when the dose is reduced
- Feeling sick or actually being sick or suffering from wind

If any of the above become serious or last more than a few days or if you notice any side

effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF MOVICOL CHOCOLATE

Sachet: Store at or below 25 °C.

Reconstituted solution: Store at 2 °C to 8 °C (in a refrigerator and keep covered). Discard any solution not used within 24 hours.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date on the label.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF MOVICOL CHOCOLATE

The powdered product is packed in 4-layer laminated sachets with label printing on both sides of the sachet. The laminate consists of paper, low density polyethylene, and aluminium foil. The sachets are sealed in pairs with a perforation line which allows for separation of the 2 sachets and are marked with the batch number and expiry date.

20 or 30 sachets are packed into an outer cardboard carton.

Not all packs and pack sizes are necessarily marketed.

IDENTIFICATION OF MOVICOL CHOCOLATE

White to light brown powder, with a characteristic chocolate odour, presented in sachets.

When made up in water, the reconstituted solution is slightly hazy.



REGISTRATION NUMBER

45/11.5/0681

**NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE
CERTIFICATE OF REGISTRATION**

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912 (South Africa)

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