

Package Leaflet: Information for the patient

MOVICOL

13.8g sachet, powder for oral solution Macrogol 3350, Sodium Chloride, Sodium Bicarbonate, Potassium Chloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.

 • If you get any side effects, talk to your
- doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet:

- What Movicol is and what it is used for
- 2. What you need to know before you take Movicol
- 3. How to take Movicol
- 4. Possible side effects
- 5. How to store Movicol
- 6. Contents of the pack and other information

1. What Movicol is and what it is used for

The name of this medicine is Movicol 13.8g sachet, powder for oral solution. It 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 helps you to have a comfortable bowel movement even if you have been constipated for a long time. Movicol also works in very bad constipation called faecal impaction.

2. What you need to know before you take Movicol

Do not take Movicol 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 the active substances or any of the other ingredients of Movicol (listed in section 6).

Warnings and precautions

When taking Movicol you should continue to take plenty of fluids. The fluid content of Movicol should not replace your regular liquid intake.

Heart conditions

Follow the special instructions in section 3 if you are taking Movicol for faecal impaction.

Other medicines and Movicol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines, e.g. anti-epileptics, may not work as effectively during use with Movicol. You should not take any other medicines by mouth together with Movicol and for one hour before and for one hour after taking Movicol. If you need to thicken fluids in order to swallow them safely, Movicol may counteract the effect of the thickener.

Pregnancy and breast feeding

Movicol can be taken during pregnancy and whilst breastfeeding. If you are pregnant, trying to become pregnant or breastfeeding, ask your pharmacist or doctor for advice before taking Movicol.

Driving and using machines

Movicol does not affect your ability to drive or use machines.

Movicol contains sodium

Talk to your doctor or pharmacist if you need 3 or more sachets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

Movicol contains 186.87 mg sodium (main component of cooking/table salt) per sachet. This is equivalent to 9.3% of the recommended maximum daily dietary intake of sodium for an adult.



3. How to take Movicol

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

Dissolve the content of each sachet in 125ml (1/4 pint) of water and drink.

Constination:

A dose of Movicol is 1 sachet dissolved in 125ml (1/4 pint) of water.

Take this 1-3 times a day according to the severity of your constipation.

Faecal impaction:

Before you take Movicol for faecal impaction, it should be confirmed that you have this condition

A dose of 8 sachets a day of Movicol is needed for the treatment of faecal impaction. Each sachet dissolved in 125ml (1/4 pint) of water. The 8 sachets should be taken within 6 hours for up to 3 days if required. If you have a heart condition, do not take more than 2 sachets in any one hour.

How to mix:

Open the sachet and pour the contents into a glass. Add about 125ml or ¼ pint of water to the glass. Stir well until all the powder has dissolved and the Movicol solution is clear or slightly hazy, then drink it. If you are taking Movicol for faecal impaction it may be easier to dissolve 8 sachets in 1 litre of water.

Duration of treatment:

Constipation:

Treatment with Movicol usually lasts for about

If you need to take Movicol for longer, please see your doctor. 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 for longer than 2 weeks. If you need to take Movicol for

longer, please see your doctor. Usually for long term treatment the dose can be lowered to either 1 or 2 sachets a day.

Faecal impaction:

Treatment with Movicol can be for up to 3 days. If you take more Movicol than you should: You may develop excessive diarrhoea, which can lead to dehydration. If this occurs, stop

taking Movicol and drink plenty of fluids. If you are worried contact your doctor or pharmacist.

If you forget to take Movicol:

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately and stop taking Movicol if you:

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

Other side effects include:

Allergic reactions which may cause a skin rash, itching, reddening of the skin or a nettle rash, swollen hands, feet or ankles, headaches and high and low levels of potassium in the blood. Sometimes you may 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. These side effects generally get better if you reduce the amount of Movicol you take.

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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Movicol

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

Do not use Movicol 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 in water, if you cannot drink it straight away keep it covered and in the fridge (2°C – 8°C). Throw away any solution not used within a 6 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.

Contents of the pack and other information

What Movicol contains

Each 13.8g sachet of Movicol contains the following:

Macrogol 3350
Sodium Chloride
Sodium Bicarbonate
Potassium Chloride
O.0466 g
Movicol also contains lime and lemon flavour, and acesulfame potassium as a sweetener.
Lemon and lime flavour contains the following ingredients: acacia solids, maltodextrin, lime oil, lemon oil, citral, citric acid and water.

When it is made into a drink with 125 millilitres of water, each sachet gives the equivalent of:

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

What Movicol looks like and contents of the pack

Movicol is available in rectangular sachets and tubular (stick-pack) sachets.

Movicol is a white powder.

Movicol is available in boxes of 2, 6, 8, 10, 20, 30, 50, 60 or 100 sachets.

Not all sachets and pack sizes may be marketed.

Marketing Authorisation Holder:

Norgine Limited Norgine House, Widewater Place, Moorhall Road, Harefield, Uxbridge, UB9 6NS, UK

Manufacturer:

Norgine Limited New Road, Tir-y-Berth, Hengoed, Mid Glamorgan, CF82 8SJ, U.K.

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria MOVICOL®-Pulver Belgium MOVICOL® Denmark MOVICOL®

Germany Macrogol Norgine Zitronen- und

Limettenaroma Pulver zur Herstellung einer Lösung zum

Finland MOVICOL®
France MOVICOL®
Iceland MOVICOL®
Ireland MOVICOL®
Italy MOVICOL® 13,8 g

MOVICOL® 13,8 g polvere per soluzione orale

Luxembourg MOVICOL® Malta MOVICOL® Netherlands MOVICOLON® MOVICOL® Norway Portugal MOVICOL® MOVICOL® Spain Sweden Movicol® United Kingdom MOVICOL®

(Northern Ireland)

This leaflet was last revised in 01/2024.

Other sources of information

If you need the information on this leaflet in an alternative format, such as large print, or Braille please ring 0800 198 5000.

MOVICOL, NORGINE and the sail logo are registered trademarks of the Norgine group of companies.



Package Leaflet: Information for the patient

MOVICOL®

13.8g sachet, powder for oral solution

Macrogol 3350, Sodium Chloride, Sodium Bicarbonate, Potassium Chloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet:

- 1. What Movicol is and what it is used for
- 2. What you need to know before you take Movicol
- 3. How to take Movicol
- 4. Possible side effects
- 5. How to store Movicol
- 6. Contents of the pack and other information

1. What Movicol is and what it is used for

The name of this medicine is Movicol 13.8g sachet, powder for oral solution. It 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 helps you to have a comfortable bowel movement even if you have been constipated for a long time. Movicol also works in very bad constipation called faecal impaction.

2. What you need to know before you take Movicol

Do not take Movicol 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 the active substances or any of the other ingredients of Movicol (listed in section 6).

Warnings and precautions

When taking Movicol you should continue to take plenty of fluids. The fluid content of Movicol should not replace your regular liquid intake.

Heart conditions

Follow the special instructions in section 3 if you are taking Movicol for faecal impaction.

Other medicines and Movicol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Some medicines, e.g. anti-epileptics, may not work as effectively during use with Movicol.

You should not take any other medicines by mouth together with Movicol and for one hour before and for one hour after taking Movicol.

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

Pregnancy and breast feeding

Movicol can be taken during pregnancy and whilst breastfeeding. If you are pregnant, trying to become pregnant or breastfeeding, ask your pharmacist or doctor for advice before taking Movicol.

Driving and using machines

Movicol does not affect your ability to drive or use machines.

Movicol contains sodium

Talk to your doctor or pharmacist if you need 3 or more sachets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet. Movicol contains 186.87 mg sodium (main component of cooking/table salt) per sachet. This is equivalent to 9.3% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Movicol

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

Dissolve the content of each sachet in 125ml (1/4 pint) of water and drink.

Constipation:

A dose of Movicol is 1 sachet dissolved in 125ml (¼ pint) of water. Take this 1 –3 times a day according to the severity of your constipation.

Faecal impaction:

Before you take Movicol for faecal impaction, it should be confirmed that you have this condition. A dose of 8 sachets a day of Movicol is needed for the treatment of faecal impaction. Each sachet dissolved in 125ml (¼ pint) of water. The 8 sachets should be taken within 6 hours for up to 3 days if required. If you have a heart condition, do not take more than 2 sachets in any one hour.

How to mix:

Open the sachet and pour the contents into a glass. Add about 125ml or ¼ pint of water to the glass. Stir well until all the powder has dissolved and the Movicol solution is clear or slightly hazy, then drink it. If you are taking Movicol for faecal impaction it may be easier to dissolve 8 sachets in 1 litre of water.

Duration of treatment:

Constipation:

Treatment with Movicol usually lasts for about 2 weeks. If you need to take Movicol for longer, please see your doctor. 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 for longer than 2 weeks. If you need to take Movicol for longer, please see your doctor. Usually for long term treatment the dose can be lowered to either 1 or 2 sachets a day.

Faecal impaction:

Treatment with Movicol can be for up to 3 days.

If you take more Movicol than you should:

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

If you forget to take Movicol:

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately and stop taking Movicol if you:

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

Other side effects include:

Allergic reactions which may cause a skin rash, itching, reddening of the skin or a nettle rash, swollen hands, feet or ankles, headaches and high and low levels of potassium in the blood.

Sometimes you may 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. These side effects generally get better if you reduce the amount of Movicol you take.

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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine

5. How to store Movicol

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

Do not use Movicol 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 in water, if you cannot drink it straight away keep it covered and in the fridge (2°C - 8°C). Throw away any solution not used within a 6 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 contains**

Each 13.8g sachet of Movicol contains the following:

13.125 g Macrogol 3350 Sodium Chloride 0.3507 g Sodium Bicarbonate 0.1785 g 0.0466 g Potassium Chloride

Movicol also contains lime and lemon flavour, and acesulfame potassium as a sweetener. Lemon and lime flavour contains the following ingredients: acacia solids, maltodextrin, lime oil, lemon oil, citral, citric acid and water.

When it is made into a drink with 125 millilitres of water, each sachet gives the equivalent of:

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

What Movicol looks like and contents of the pack

Movicol is available in rectangular sachets and tubular (stick-pack) sachets.

Movicol is a white powder.

Movicol is available in boxes of 2, 6, 8, 10, 20, 30, 50, 60 or 100 sachets.

Not all sachets and pack sizes may be marketed.

Marketing Authorisation Holder:

Norgine Limited, Norgine House, Widewater Place, Moorhall Road, Harefield, Uxbridge, UB9 6NS, UK

Manufacturer:

Sophartex, 21 rue du Pressoir, 28500 Vernouillet, France.

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

MOVICOL®-Pulver Austria MOVICOL® Belgium MOVICOL® Denmark

Germany Macrogol Norgine Zitronen- und

Limettenaroma Pulver zur Herstellung

einer Lösung zum Einnehmen

MOVICOL® **Finland** MOVICOL® France MOVICOL® Iceland MOVICOL® Ireland

MOVICOL® 13,8 g polvere per Italy

soluzione orale

MOVICOL® Luxembourg MOVICOL® Malta MOVICOLON® MOVICOL® Netherlands Norway MOVICOL® Portugal MOVICOL® Spain Movicol[®] Sweden MOVICOL® United Kinadom

(Northern Ireland)

This leaflet was last revised in 01/2024.

Other sources of information

If you need the information on this leaflet in an alternative format, such as large print, or Braille please ring 0800 198 5000.

MOVICOL, NORGINE and the sail logo are registered trademarks of the Norgine group of companies.



XXXXXX

MOVICOL

13.8g sachet, powder for oral solution Macrogol 3350, Sodium Chloride,

Sodium Bicarbonate, Potassium Chloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet:

- 1. What Movicol is and what it is used for
- What you need to know before you take Movicol
- 3. How to take Movicol
- 4. Possible side effects
- How to store Movicol
- 6. Contents of the pack and other information

1. What Movicol is and what it is used for

The name of this medicine is Movicol 13.8g sachet, powder for oral solution. It 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 helps you to have a comfortable bowel movement even if you have been constipated for a long time. Movicol also works in very bad constipation called faecal impaction.

2. What you need to know before you take Movicol

Do not take Movicol 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 the active substances or any of the other ingredients of Movicol (listed in section 6).

Warnings and precautions

When taking Movicol you should continue to take plenty of fluids. The fluid content of Movicol should not replace your regular liquid intake.

Heart conditions

Follow the special instructions in section 3 if you are taking Movicol for faecal impaction.

Other medicines and Movicol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Some medicines, e.g. anti-epileptics, may not work as effectively during use with Movicol.

You should not take any other medicines by mouth together with Movicol and for one hour before and for one hour after taking Movicol.

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

Pregnancy and breast feeding

Movicol can be taken during pregnancy and whilst breastfeeding. If you are pregnant, trying to become pregnant or breastfeeding, ask your pharmacist or doctor for advice before taking Movicol.

Driving and using machines

Movicol does not affect your ability to drive or use machines

Movicol contains sodium

Talk to your doctor or pharmacist if you need 3 or more sachets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet. Movicol contains 186.87 mg sodium (main component of cooking/table salt) per sachet. This is equivalent to 9.3% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Movicol

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

Dissolve the content of each sachet in 125ml (1/4 pint) of water and drink.

A dose of Movicol is 1 sachet dissolved in 125ml (1/4 pint) of water. Take this 1-3 times a day according to the severity of your constipation.

Faecal impaction:

Before you take Movicol for faecal impaction, it should be confirmed that you have this condition. A dose of 8 sachets a day of Movicol is needed for the treatment of faecal impaction. Each sachet dissolved in 125ml (1/4 pint) of water. The 8 sachets should be taken within 6 hours for up to 3 days if required. If you have a heart condition, do not take more than 2 sachets in any one hour.

How to mix:

Open the sachet and pour the contents into a glass. Add about 125ml or ¼ pint of water to the glass. Stir well until all the powder has dissolved and the Movicol solution is clear or slightly hazy, then drink it. If you are taking Movicol for faecal impaction it may be easier to dissolve 8 sachets in 1 litre of water.

Duration of treatment:

Constipation:

Treatment with Movicol usually lasts for about 2 weeks. If you need to take Movicol for longer, please see your doctor. 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 for longer than 2 weeks. If you need to take Movicol for longer, please see your doctor. Usually for long term treatment the dose can be lowered to either 1 or 2 sachets a day.

Faecal impaction:

Treatment with Movicol can be for up to 3 days.

If you take more Movicol than you should:

You may develop excessive diarrhoea, which can lead to dehydration. If this occurs, stop taking

Movicol and drink plenty of fluids. If you are worried contact your doctor or pharmacist.

If you forget to take Movicol:

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Tell your doctor immediately and stop taking Movicol if you:

• Get a serious allergic reaction which causes • Get a serious allergic reaction which causes

difficulty in breathing, or swelling of the face, lips, tongue or throat.

Other side effects include:

Allergic reactions which may cause a skin rash, itching, reddening of the skin or a nettle rash, swollen hands, feet or ankles, headaches and high and low levels of potassium in the blood.

Sometimes you may 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. These side effects generally get better if you reduce the amount of Movicol you take.

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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Movicol

Keep this medicine out of the sight and reach of children

Do not use Movicol 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 in water, if you cannot drink it straight away keep it covered and in the fridge (2°C – 8°C). Throw away any solution not used within a 6 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 contains**

Each 13.8g sachet of Movicol contains the following:

Macrogol 3350 13.125 g Sodium Chloride 0.3507 g Sodium Bicarbonate 0.1785 g Potassium Chloride 0.0466 g

Movicol also contains lime and lemon flavour, and acesulfame potassium as a sweetener. Lemon and lime flavour contains the following ingredients: acacia solids, maltodextrin, lime oil, lemon oil, citral, citric acid and water.

When it is made into a drink with 125 millilitres of water, each sachet gives the equivalent of:

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

What Movicol looks like and contents of the pack Movicol is available in rectangular sachets and tubular (stick-pack) sachets.

Movicol is a white powder.

Movicol is available in boxes of 2, 6, 8, 10, 20, 30, 50, 60 or 100 sachets.

Not all sachets and pack sizes may be marketed.

Marketing Authorisation Holder:

Norgine Limited, Norgine House, Widewater Place, Moorhall Road, Harefield, Uxbridge, UB9 6NS, UK

Manufacturer:

Laboratoires Macors, Rue des Caillottes, Zi De La Plaine Des Isles, 89000 Auxerre, France.

This medicine is authorised in the Member States of the **European Economic Area and in the United Kingdom** (Northern Ireland) under the following names:

MOVICOL®-Pulver Austria MOVICOL® Belgium $MOVICOL^{\tiny{\scriptsize{\scriptsize{\scriptsize{0}}}}}$ Denmark

Macrogol Norgine Zitronen- und Germany

> Limettenaroma Pulver zur Herstellung einer Lösung zum

Einnehmen MOVICOL® **Finland** MOVICOL® France $\mathsf{MOVICOL}^{\mathbb{R}}$ Iceland MOVICOL® Ireland

MOVICOL® 13,8 g polvere per Italy

soluzione orale MOVICOL®

Luxembourg $\mathsf{MOVICOL}^{\small{\mathbb{R}}}$ Malta MOVICOLON® MOVICOL® Netherlands Norway MOVICOL® Portugal $\mathsf{MOVICOL}^{\mathbb{R}}$ Spain Movicol[®] Sweden United Kingdom MOVICOL®

(Northern Ireland)

This leaflet was last revised in 01/2024.

Other sources of information

If you need the information on this leaflet in an alternative format, such as large print, or Braille please ring 0800 198 5000.

MOVICOL, NORGINE and the sail logo are registered trademarks of the Norgine group of companies.

NORGINE 33396102 XXXXX FPO



Package Leaflet: Information for the patient

MOVICOL®

13.8g sachet, powder for oral solution

Macrogol 3350, Sodium Chloride, Sodium Bicarbonate, Potassium Chloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet:

- 1. What Movicol is and what it is used for
- 2. What you need to know before you take Movicol
- 3. How to take Movicol
- 4. Possible side effects
- 5. How to store Movicol
- 6. Contents of the pack and other information

1. What Movicol is and what it is used for

The name of this medicine is Movicol 13.8g sachet, powder for oral solution. It 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 helps you to have a comfortable bowel movement even if you have been constipated for a long time. Movicol also works in very bad constipation called faecal impaction.

2. What you need to know before you take Movicol Do not take Movicol 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 the active substances or any of the other ingredients of Movicol (listed in section 6).

Warnings and precautions

When taking Movicol you should continue to take plenty of fluids. The fluid content of Movicol should not replace your regular liquid intake.

Heart conditions

Follow the special instructions in section 3 if you are taking Movicol for faecal impaction.

Other medicines and Movicol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines, e.g. anti-epileptics, may not work as effectively during use with Movicol.

You should not take any other medicines by mouth together with Movicol and for one hour before and for one hour after taking Movicol.

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

Pregnancy and breast feeding

Movicol can be taken during pregnancy and whilst breastfeeding. If you are pregnant, trying to become pregnant or breastfeeding, ask your pharmacist or doctor for advice before taking Movicol.

Driving and using machines

Movicol does not affect your ability to drive or use machines.

Movicol contains sodium

Talk to your doctor or pharmacist if you need 3 or more sachets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

Movicol contains 186.87 mg sodium (main component of cooking/table salt) per sachet. This is equivalent to 9.3% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Movicol

This medicine can be taken at any time with or without food. Dissolve the content of each sachet in 125 ml ($\frac{1}{4}$ pint) of water and drink.

Constipation:

A dose of Movicol is 1 sachet dissolved in 125 ml (1/4 pint) of water

Take this 1 –3 times a day according to the severity of your constipation.

Faecal impaction:

Before you take Movicol for faecal impaction, it should be confirmed that you have this condition.

A dose of 8 sachets a day of Movicol is needed for the treatment of faecal impaction. Each sachet dissolved in 125 ml (¼ pint) of water.

The 8 sachets should be taken within 6 hours for up to 3 days if required. If you have a heart condition, do not take more than 2 sachets in any one hour.

How to mix

Open the sachet and pour the contents into a glass. Add about 125 ml or ¼ pint of water to the glass. Stir well until all the powder has dissolved and the Movicol solution is clear or slightly hazy, then drink it. If you are taking Movicol for faecal impaction it may be easier to dissolve 8 sachets in 1 litre of water

Duration of treatment:

Constipation:

Treatment with Movicol usually lasts for about 2 weeks. If you need to take Movicol for longer, please see your doctor. 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 for longer than 2 weeks. If you need to take Movicol for longer, please see your doctor. Usually for long term treatment the dose can be lowered to either 1 or 2 sachets a day.

Faecal impaction:

Treatment with Movicol can be for up to 3 days.

If you take more Movicol than you should:

You may develop excessive diarrhoea, which can lead to dehydration. If this occurs, stop taking Movicol and drink plenty of fluids.

If you are worried contact your doctor or pharmacist. If you forget to take Movicol:

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately and stop taking Movicol if you:

• Get a serious allergic reaction which causes difficulty in breathing, or swelling of the face, lips, tongue or throat. Other side effects include:

Allergic reactions which may cause a skin rash, itching, reddening of the skin or a nettle rash, swollen hands, feet or ankles, headaches and high and low levels of potassium in the blood.

Sometimes you may 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. These side effects generally get better if you reduce the amount of Movicol you take.

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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Movicol

Keep this medicine out of the sight and reach of children. Do not use Movicol 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 in water, if you cannot drink it straight away keep it covered and in the fridge (2°C – 8°C). Throw away any solution not used within a 6 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 contains

Each 13.8g sachet of Movicol contains the following:

Macrogol 3350 13.125 g

Sodium Chloride 0.3507 g

Sodium Bicarbonate 0.1785 g

Potassium Chloride 0.0466 g

Movicol also contains lime and lemon flavour, and

acesulfame potassium as a sweetener.

Lemon and lime flavour contains the following ingredients: acacia solids, maltodextrin, lime oil, lemon oil, citral, citric acid and water.

When it is made into a drink with 125 millilitres of water, each sachet gives the equivalent of:

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

What Movicol looks like and contents of the pack

Movicol is available in rectangular sachets and tubular (stick-pack) sachets.

Movicol is a white powder.

Movicol is available in boxes of 2, 6, 8, 10, 20, 30, 50, 60 or 100 sachets. Not all sachets and pack sizes may be marketed.

Marketing Authorisation Holder:

Norgine Limited

Norgine House, Widewater Place, Moorhall Road, Harefield, Uxbridge, UB9 6NS, UK

Manufacturer:

Norgine Limited

New Road, Tir-y-Berth, Hengoed, Mid Glamorgan, CF82 8SJ, U.K.

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria MOVICOL®-Pulver
Belgium MOVICOL®
Denmark MOVICOL®

Germany Macrogol Norgine Zitronen- und

Limettenaroma Pulver zur Herstellung

einer Lösung zum Einnehmen Finland MOVICOL®

France MOVICOL®
Iceland MOVICOL®
Ireland MOVICOL®
Italy MOVICOL® 13,8 g

polvere per soluzione orale

Luxembourg MOVICOL®
Malta MOVICOL®
Netherlands MOVICOLON®
Norway MOVICOL®
Portugal MOVICOL®
Spain MOVICOL®
Sweden Movicol®
United Kingdom MOVICOL®

(Northern Ireland)

This leaflet was last revised in 01/2024.

Other sources of information

If you need the information on this leaflet in an alternative format, such as large print, or Braille please ring 0800 198 5000.

MOVICOL, NORGINE and the sail logo are registered trademarks of the Norgine group of companies.

