

Package Leaflet: Information for the patient

MOVICOL®

Liquid Orange flavour

Concentrate for oral solution

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.

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

What is in this leaflet:

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

1. What Movicol Liquid Orange flavour is and what it is used for

The name of this medicine is Movicol liquid Orange flavour concentrate for oral solution.

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

Movicol liquid Orange flavour helps you to have a comfortable bowel movement even if you have been constipated for a long time.

You must not use Movicol liquid Orange flavour if you have a very bad constipation called faecal impaction

2. What you need to know before you take Movicol Liquid Orange flavour

Do not take Movicol Liquid Orange flavour 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 liquid Orange flavour (listed in section 6).

Other medicines and Movicol Liquid Orange flavour

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

Some medicines, e.g. anti-epileptics, (medicines for epilepsy) may not work as effectively during use with Movicol liquid Orange flavour.

Pregnancy and breast-feeding

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

Driving and using machines

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

Important information about some of the ingredients of Movicol liquid Orange flavour

This medicinal product contains ethyl and methyl parahydroxybenzoate which may cause allergic reactions, possibly delayed.

It also contains:

- small amounts of ethanol (alcohol), less than 100 mg per 25 ml dose.
- 45.6 mg of benzyl alcohol in each diluted dose of 125 ml.

Do not exceed the stated dose.

3. How to take Movicol Liquid Orange flavour

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

This product must be diluted before use.

A dose of Movicol liquid Orange flavour is 25 ml liquid diluted in 100 ml of water.

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

How to mix:

Open the bottle and measure 25 ml or five 5 ml teaspoonfuls. Pour the liquid into a glass and then add 100ml (about half a glassful) of water. Stir well until all the liquid has been evenly mixed and the diluted Movicol liquid Orange flavour solution is clear, then drink it.

Please rinse the dosing cup after use and replace on the bottle.

Duration of treatment:

Treatment with Movicol liquid Orange flavour usually lasts for about 2 weeks. If you need to take Movicol liquid Orange flavour 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 liquid Orange flavour for longer than 2 weeks.

Usually for long term treatment the dose can be lowered to either 1 or 2 doses a day.

If you take more Movicol liquid Orange flavour than you should

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

If you forget to take Movicol liquid Orange flavour

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.

If you have a serious allergic reaction which causes difficulty in breathing, or swelling of the face, lips, tongue or throat, tell your doctor **immediately** and **stop** taking Movicol liquid Orange flavour. Other allergic reactions may occur which may cause a skin rash, itching, reddening of the skin or a nettle rash, swollen hands, feet or ankles and headache.

Other side effects may also include indigestion, stomach ache or rumbles and high and low levels of potassium in the blood. 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 liquid Orange flavour which generally gets better if you reduce the amount of Movicol liquid Orange flavour 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Movicol Liquid Orange Flavour

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

Do not use Movicol liquid Orange flavour after the expiry date which is stated on the bottle. The expiry date refers to the last day of that month.

Do not refrigerate or freeze.

Discard any remaining product 30 days after first opening the bottle.

Once you have diluted Movicol liquid Orange flavour in water, if you cannot drink it straight away keep it covered. 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 liquid Orange flavour contains

Each 25 ml of Movicol liquid Orange flavour contains the following:

| | |
|---------------------------|----------|
| Macrogol 3350 | 13.125 g |
| Sodium Chloride | 0.3507 g |
| Sodium Hydrogen Carbonate | 0.1785 g |
| Potassium Chloride | 0.0466 g |

Movicol liquid Orange flavour also contains purified water, orange flavour, and acesulfame potassium (E950) and sucralose (E955) as sweeteners.

It also contains a preservative which contains benzyl alcohol,

methyl parahydroxybenzoate (E218) and ethyl parahydroxybenzoate (E214).

Orange flavour contains the following ingredients: flavouring substances, flavouring preparations and ethanol (alcohol).

When each 25 ml is made into a drink with 100 millilitres of water, it gives the equivalent of:

| | |
|--------------------|----------------------|
| Sodium | 65 millimoles/litre |
| Chloride | 53 millimoles/litre |
| Potassium | 5.4 millimoles/litre |
| Hydrogen Carbonate | 17 millimoles/litre |

Movicol liquid Orange flavour contains 8.125 mmol of sodium in each diluted dose of 125 ml. To be taken into consideration by patients on a controlled sodium diet.

What Movicol liquid Orange flavour looks like and contents of the pack

Movicol Liquid Orange flavour is a clear, colourless liquid.

Each pack consists of a carton with a plastic bottle of Movicol liquid Orange flavour containing 500 ml of solution and a plastic dosing cup.

Marketing Authorisation Holder

Norgine Pharmaceuticals Limited,
Widewater place, Moorhall Road,
Harefield, Middlesex UB9 6NS, UK

Manufacturer:

Norgine Pharma Dreux, 29, Rue Ethé Virton,
28109 Dreux Cedex, France

or

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



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

| | |
|----------------|--|
| Austria | MOVICOL® Liquid Orange |
| Belgium | MOVICOL® Vloeibaar Sinaasappelsmaak MOVICOL® Liquide Goût orange MOVICOL® Flüssig Orangengeschmack |
| Germany | Macrogol Norgine Orangengeschmack Konzentrat zur Herstellung einer Lösung zum Einnehmen |
| Finland | MOVICOL® Appelsiini |
| Ireland | MOVICOL® Liquid Orange flavour |
| Italy | MOVICOL® 13,9 g/25 ml concentrato per soluzione orale, gusto Arancio |
| Luxembourg | MOVICOL® Liquide Goût orange |
| Netherlands | MOVICOLON® Liquid Orange |
| Portugal | MOVICOL® Laranja |
| Spain | MOVICOL® Sabor Naranja Solución /Concentrado para solución oral |
| Sweden | MOVICOL® Apelsin |
| Switzerland | MOVICOL® Liquid Orange |
| United Kingdom | MOVICOL® Liquid Orange flavour |

MOVICOL is a registered trademark of the Norgine group of companies.