

Package Leaflet: Information for the patient

Movicol® Apelsin, Concentrate for oral solution

Macrogol 3350, Sodium Chloride, Sodium Hydrogen Carbonate, 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 Apelsin is and what it is used for
2. What you need to know before you take Movicol Apelsin
3. How to take Movicol Apelsin
4. Possible side effects
5. How to store Movicol Apelsin
6. Contents of the pack and other information

1. What Movicol Apelsin is and what it is used for

The name of this medicine is Movicol Apelsin 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 Apelsin helps you to have a comfortable bowel movement even if you have been constipated for a long time.

You must not use Movicol Apelsin if you have a very bad constipation called faecal impaction.

2. What you need to know before you take Movicol Apelsin

Do not take Movicol Apelsin 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 Apelsin (listed in section 6).

Warnings and precautions

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

Other medicines and Movicol Apelsin

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 Apelsin.

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

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

Pregnancy and breast-feeding

Movicol Apelsin 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 Apelsin.

Driving and using machines

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

Movicol Apelsin contains ethyl parahydroxybenzoate, methyl parahydroxybenzoate, alcohol (ethanol), benzyl alcohol and sodium

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

This medicine contains 74.6 mg of alcohol (ethanol) in 25 ml concentrate for oral solution, which is equivalent to 3.0 mg of alcohol (ethanol) per ml. The amount in 25 ml concentrate for oral solution of this medicine is equivalent to less than 2 ml of beer or 1 ml of wine. The small amount of alcohol in this medicine will not have any noticeable effects.

This medicine contains 45.6 mg of benzyl alcohol in each diluted dose of 125 ml. Benzyl alcohol may cause allergic reactions.

Ask your doctor or pharmacist for advice if you have a liver or kidney disease, are pregnant or breastfeeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

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

Movicol Apelsin contains 186.87 mg sodium (main component of cooking/table salt) per 25 ml dose. This is equivalent to 9.3% of the recommended maximum daily dietary intake of sodium for an adult.

Do not exceed the stated dose.

3. How to take Movicol Apelsin

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

This product must be diluted before use.

A dose of Movicol Apelsin 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 Apelsin solution is clear, then drink it.

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

Duration of treatment:

Treatment with Movicol Apelsin usually lasts for about 2 weeks. If you need to take Movicol Apelsin 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 Apelsin 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 Apelsin than you should

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

If you forget to take Movicol Apelsin

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 Apelsin.

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 and 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 Apelsin which generally gets better if you reduce the amount of Movicol Apelsin 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 the **national reporting system listed in Appendix V***. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Movicol Apelsin

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

Do not use Movicol Apelsin 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 Apelsin 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 Apelsin contains

Each 25 ml of Movicol Apelsin 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 Apelsin also contains purified water, orange flavour, and acesulfame potassium (E950) and sucralose (E955) as sweeteners.

It also contains a preservative which contains benzyl alcohol (E1519), methyl parahydroxybenzoate (E218) and ethyl parahydroxybenzoate (E214). See section 2 “Movicol Apelsin contains ethyl parahydroxybenzoate, methyl parahydroxybenzoate, alcohol (ethanol), benzyl alcohol and sodium”.

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

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

What Movicol Apelsin looks like and contents of the pack

Movicol Apelsin is a clear, colourless liquid.

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

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer:

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

This medicine is authorised in the Member States of the European Economic Area 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
Portugal	MOVICOL Laranja
Spain	Movicol Sabor Naranja concentrado para solución oral
Sweden	Movicol Apelsin

This leaflet was last revised in 02/2025.