



Package leaflet: Information for the Patient

**STRIGOL ORANGE Flavour
13.72 g 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.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Strigol Orange Flavour is and what it is used for

The name of this medicine is Strigol Orange Flavour 13.72g powder for oral solution. It is a laxative for the treatment of chronic constipation in adults, adolescents and elderly and for the treatment of very bad constipation (called faecal impaction).

It is not recommended for children below 12 years of age.

Strigol Orange Flavour helps you to have a comfortable bowel movement even if you have been constipated for a long time.

2. What you need to know before you take Strigol Orange Flavour

Do not take Strigol Orange Flavour:

- if you are allergic to macrogol, sodium chloride, sodium bicarbonate, potassium chloride or any of the other ingredients in this medicine (listed in section 6).
- if you have a blockage in the intestine (gut obstruction, ileus)
- if you have a perforated gut wall
- if you have severe inflammatory bowel disease like ulcerative colitis, Crohn's disease or toxic megacolon.

Warnings and precautions

Talk to your doctor or pharmacist before taking Strigol Orange Flavour.

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

Avoid mixing Strigol Orange Flavour and starch-based food thickeners if you have difficulties with swallowing. This may result in a watery liquid which could get into your lungs and cause pneumonia if you can't swallow properly.

Strigol Orange Flavour contains 0.6213 mmol (24.230 mg) of potassium per sachet. This should be taken into consideration if the patient takes more than one sachet daily and has reduced kidney function, or is on a controlled potassium diet.

If you develop side effects such as swelling, shortness of breath, feeling tired, dehydration (symptoms include increasing thirst, dry mouth and weakness) or heart problems you should stop taking Strigol Orange and contact your doctor immediately.

Heart conditions

Follow the special instructions in section 3 if you are taking Strigol Orange Flavour for faecal impaction.

Children

This medicine is not recommended for children below 12 years of age.

Other medicines and Strigol 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, may not work as effectively during use with Strigol Orange Flavour.

Strigol Orange Flavour with food and drink

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

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

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Strigol Orange Flavour can be taken during pregnancy and whilst breast-feeding.

Driving and using machines

Strigol Orange Flavour does not affect your ability to drive or use machines.

Strigol Orange Flavour 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 Strigol Orange Flavour

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

Chronic Constipation:

For adults, adolescents and the elderly the recommended dose is 1 sachet, 1–3 times a day according to the severity of your constipation.

Faecal impaction:

Before you take Strigol Orange Flavour for faecal impaction, your doctor must check to confirm that you have this condition.

For adults, adolescents and the elderly the recommended dose is 8 sachets a day. All the 8 sachets should be taken within 6 hours, and for up to 3 days if required. If you have a heart conditions do not take more than 2 sachets per one hour.



160 x 300 mm

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Front Page

ARTWORK DETAIL LABEL

Product	Strigol Orange flavour 13.72g powder for oral solution			
Buyer/Country	Strides Pharma UK Ltd.	Component	Pack Insert	
Dimension	160 x 300 mm		Pack	--
New Item Code	1046253	Old Item Code	1041686	
Colour Shades	Black	No. of Colours	1	
Change Control No.	PC-TSG/2021/369 - Record Number: 305208 and 326106		Artwork Version	2.0
Design/Style	Front & Back Printing. To be supplied in folded size: 80 x 75 mm			
Substrate	60 GSM Paper.			
Special Instructions	Printing clarity to be clear & sharp.			
Autocartanator Requirements	NA			
Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.				

Method of Administration

- Open the sachet and pour the contents into a glass.
- Add ½ glass (about 125ml) of water.
- Stir well until all the powder has dissolved and the Strigol Orange Flavour solution is clear or slightly hazy, then drink it.

If you are taking Strigol Orange Flavour for faecal impaction it may be easier to dissolve 8 sachets in 1 litre of water.

Duration of treatment

Chronic constipation:

Treatment with Strigol Orange Flavour usually lasts for about 2 weeks. If you need to take Strigol 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 Strigol Orange Flavour for longer than 2 weeks.

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

Faecal impaction:

Treatment with Strigol Orange Flavour can be for up to 3 days.

If you take more Strigol Orange Flavour than you should

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

If you forget to take Strigol Orange Flavour

Take the dose as soon as you remember.

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 Strigol Orange Flavour if you:

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

Not known (frequency cannot be estimated from the available data):

- change in your body's fluid or electrolyte levels (low levels of potassium, low levels of sodium)

Other side effects include:

- indigestion
- stomach pains
- stomach rumbles
- mild diarrhoea (when starting taking Strigol Orange Flavour)
- vomiting (being sick)
- nausea (feeling sick)
- anal discomfort (uncomfortable sensation around the bottom)
- swollen stomach
- wind

These side effects generally get better if you reduce the amount Strigol Orange Flavour you take.

- allergic reactions which may cause a skin rash (hives), 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.

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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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 Strigol Orange Flavour

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

Do not use this medicine after the expiry date which is stated on the sachet. The expiry date refers to the last day of that month.

Unopened sachet: No special storage conditions.

Once you have made up Strigol Orange Flavour in water, if you cannot drink it straight away keep it covered and in the fridge (2 – 8°C). 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 any medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Strigol Orange Flavour contains

Each 13.72 g sachet of Strigol Orange Flavour contains the following:

Macrogol 3350	13.125 g
Sodium chloride	350.7 mg
Sodium bicarbonate	178.5 mg
Potassium chloride	46.6 mg

The other ingredients are Acesulfame potassium and orange flavor.

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

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

What Strigol Orange Flavour looks like and contents of the pack

Strigol Orange Flavour is a white crystalline powder in single-dose sachets with orange odour. Boxes of 6, 8, 10, 20, 30, 40, 50, 60 or 100 sachets are available.

Not all pack sizes will be marketed.

Marketing Authorisation holder and Manufacturer:

Strides Pharma UK Ltd.
Unit 4, Metro Centre, Tolpits Lane, Watford,
Hertfordshire, WD18 9SS,
United Kingdom.

This leaflet was last revised in 11/2021.



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