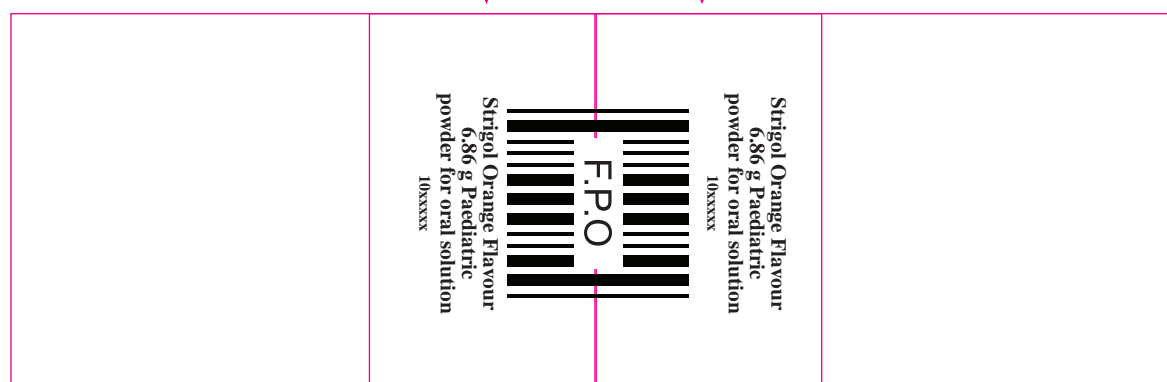


Artwork for Submission purpose: UK Market

Position / Orientation shall be changed depending upon the Printer's Machine suitability.



Package leaflet: Information for the Patient

Strigol Orange Flavour 6.86 g Paediatric powder for oral solution
macrogol 3350, sodium chloride, sodium bicarbonate, potassium chloride

Read all of this leaflet carefully before you give this medicine to your child.

- 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 your child. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child gets any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not included in this leaflet. See section 4.

What is in this leaflet:

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

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

The name of this medicine is Strigol Orange Flavour 6.86 g Paediatric powder for oral solution.

It is a laxative for the treatment of chronic constipation in children aged 2 to 11 years and for the treatment of very bad constipation (called faecal impaction) in children aged 5 to 11 years. Strigol Orange Flavour Paediatric also prevents re-impaction after successful disimpaction in children 2 to 11 years of age.

Strigol Orange Flavour Paediatric helps your child to have a comfortable bowel movement even if they have been constipated for a long time.

2. What do you need to know before you give Strigol Orange Flavour Paediatric

Do not give Strigol Orange Flavour Paediatric if your doctor has told you that your child has:

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

If your child has a heart or kidney problem, an impaired gag reflex or reflux oesophagitis (heart-burn caused by back-flow of stomach contents into the oesophagus), you should talk to your doctor before giving Strigol Orange Flavour Paediatric.

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 Flavour Paediatric and contact your doctor immediately.

Warnings and precautions

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

Avoid mixing Strigol Orange Flavour Paediatric

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 Paediatric contains 0.3106 mmol (12.11 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.

Other medicines and Strigol Orange Flavour Paediatric

Tell your doctor or pharmacist if your child is taking or has 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 Paediatric. When taking large volumes of Strigol Orange Flavour Paediatric (e.g. for faecal impaction), your child should not take other medicines within one hour of taking Strigol Orange Flavour Paediatric.

Strigol Orange Flavour Paediatric 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 Paediatric may counteract the effect of the thickener.

Pregnancy and breast-feeding

Strigol Orange Flavour Paediatric can be given during pregnancy and whilst breast feeding. If your child is pregnant or breastfeeding, ask your doctor before giving this medicine.

Strigol Orange Flavour Paediatric contains about 93.4 mg sodium (main component of cooking/table salt) per sachet. This is equivalent to 4.6% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to give Strigol Orange Flavour Paediatric

Always give this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

Chronic Constipation:

The dose of Strigol Orange Flavour Paediatric depends on the age of the child and their response to treatment.

- As a starting dose, children aged 2 to 6 years should be given 1 sachet each day.
- Children aged 7 to 11 should be given 2 sachets each day.

Your doctor may tell you to increase the number of sachets taken until your child has a soft bowel movement. If the dose does need increasing, this should be done every other day. Normally, no more than 4 sachets are required to be taken in one day.

It is not necessary to take all of the drink at one time, if the child prefers it, half the drink can be taken in the morning and half in the evening.

Faecal impaction:

Before your child takes Strigol Orange Flavour Paediatric for faecal impaction, it should be confirmed medically that your child has this condition.

A course of treatment with Strigol Orange Flavour Paediatric is as follows:

155 x 350 mm

FRONT SIDE

Strigol Orange Flavour - Pack Insert - SPUK - Submission

Dimension: 155 x 350 mm

Folded Dimension: 30 x 50 mm (with glue)

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Age (years)	Number of Strigol Orange Flavour Paediatric sachets						
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
5-11	4	6	8	10	12	12	12

The daily number of sachets should be taken in divided doses, all taken within 12 hours (e.g. 8am – 8pm). Treatment can be stopped when the medicine has worked. This is shown by your child passing large volumes of stool and/or watery diarrhoea.

Method of Administration

- Open the sachet and pour the contents into a glass.
- Add ¼ glass (about 62.5ml) of water.
- Stir well until all the powder has dissolved and the Strigol Orange Flavour Paediatric solution is clear or slightly hazy, then give it to your child to drink.

Duration of treatment

Chronic constipation:

Treatment needs to be for a prolonged period of time, at least 6 – 12 months.

Faecal impaction:

Treatment with Strigol Orange Flavour Paediatric can be for up to 7 days.

If your child takes more Strigol Orange Flavour Paediatric than they should:

Your child may develop excessive diarrhoea. If this occurs, stop taking Strigol Orange Flavour Paediatric and drink plenty of fluids. If you are worried contact your doctor or pharmacist.

If you forget to give Strigol Orange Flavour Paediatric:

Give 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 giving Strigol Orange Flavour Paediatric if your child:

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

Very common side effects (may affect more than 1 in 10 people)

- stomach pains
- stomach rumbles

Common side effects (may affect up to 1 in 10 people)

- diarrhoea
- vomiting (being sick)
- nausea (feeling sick)
- anal discomfort (uncomfortable sensation around the bottom).

If your child is being treated for **chronic constipation**, diarrhoea will usually improve when the dose is reduced.

Uncommon side effects (may affect up to 1 in 100 people)

- swollen stomach
- wind

Rare side effects (may affect up to 1 in 1000 people)

- allergic reactions, which may include, breathlessness or difficulty in breathing.

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 reported include:

Skin rash (hives), itching, reddening of the skin

or a nettle rash, swollen hands, feet or ankles, headaches, indigestion, high or 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 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 Strigol Orange Flavour Paediatric

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 and carton. The expiry date refers to the last day of that month.

Once you have made up Strigol Orange Flavour Paediatric in water, if your child 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 house hold waste. Ask your pharmacist how to throw away of medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Strigol Orange Flavour Paediatric contains:

Each 6.86g sachet of Strigol Orange Flavour Paediatric contains the following:

Macrogol 3350	6.563 g
Sodium Chloride	175.4 mg
Sodium Bicarbonate	89.3 mg
Potassium Chloride	23.30 mg

The other ingredients are Acesulfame potassium and Orange flavor.

When it is made into a drink with ¼ glass (62.5ml) of water, each sachet gives the equivalent of:

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

What Strigol Orange Flavour Paediatric looks like and contents of the pack

Strigol Orange Flavour Paediatric 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 The Metro Centre,
Dwight Road, Watford, WD18 9SS
United Kingdom

This leaflet was last revised in 02/2024.

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155 x 350 mm

BACK SIDE

Strigol Orange Flavour - Pack Insert - SPUK - Submission

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