

Artwork for Submission purpose: UK Market

	Number of Strigol Orange Flavour Paediatric sachets						
Age (years)	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
Potassium Bicarbonate	53 millimoles/litre
	5.4 millimoles/litre
	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.

155 x 350 mm

BACK SIDE

Strigol Orange Flavour - Pack Insert - SPUK - Submission

Dimension: 155 x 350 mm

Folded Dimension: 30 x 50 mm (with glue)

Market: SPUK

Version: 01

Date: 23.02.2024