

FYBOGEL HI-FIBRE ORANGE

Ispaghula Husk 3.5g

PATIENT INFORMATION LEAFLET

Read 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 or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- **You must talk to a doctor if your symptoms worsen or do not improve after 3 days.**
- 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 Fybogel Hi-Fibre Orange is and what it is used for
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1. What Fybogel Hi-Fibre Orange is and what it is used for

Fybogel Hi-Fibre Orange contains the active substance Ispaghula Husk. It is an easy and convenient way to increase the fibre in your diet helping your digestive system work more efficiently and gently relieving constipation the natural way. As it works naturally with your body, it takes care of constipation without undue straining, discomfort or unnatural urgency, helping to restore and maintain regularity.

Fybogel Hi-Fibre Orange can be used whenever increased fibre is needed in your diet to relieve constipation; including constipation during pregnancy. It can also be used to help maintain normal bowel function if you suffer from haemorrhoids (piles).

2. What you need to know before you take Fybogel Hi-Fibre Orange

Do not take if:

- you are allergic to Ispaghula husk or any of the other ingredients (see section 6)
- You have a sudden change in bowel habit that has persisted for more than two weeks.
- you are suffering from a blockage of the bowel (intestinal obstruction, faecal impaction)
- if you have a weakness of the bowel wall (colonic atony)
- the speed in which material moves through your gut has always been slow (naturally occurring reduced gut motility).
- You have difficulty in swallowing or any throat problems

Tell your doctor, pharmacist or nurse if:

- you have phenylketonuria (an inherited genetic disorder) as this product contains aspartame, a source of phenylalanine.
- You are suffering from undiagnosed rectal bleeding and unable to pass stools following the use of laxatives.
- your symptoms worsen or do not improve after 3 days.

If stomach pain occurs or in cases of a sudden change in bowel habit please stop using this product and speak to your doctor.

Take special care:

- if you are a healthcare worker or care giver as allergic sensitisation may occur due to inhalation.
- if not taken with enough liquid, can cause chest pain, vomiting or difficulty swallowing.
- elderly and debilitated (weak) patients may require medical supervision.

Other medicines and Fybogel Hi-Fibre Orange :

You must not take this medicine if you are taking other medicines which may cause constipation (e.g. codeine or morphine).

Do not take Fybogel Hi-Fibre Orange within ½ to 1 hour before or after the following medicines.

- Insulin - if you are diabetic and use insulin, you may need to reduce your dose of insulin if you take Fybogel Hi-Fibre Orange with meals.
- medicines for thyroid problems - your doctor may need to change the dose of the thyroid hormones you are taking.

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Pregnancy and breast-feeding :

This medicine may be used during pregnancy and breast-feeding.

This medicine contains 16mg aspartame in each sachet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

This medicine contains less than 1 mmol sodium (23 mg) in each sachet, that is to say essentially 'sodium-free'.

This medicine contains 0.25 mmol (or 9.76 mg) potassium per sachet. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

3. How to take Fybogel Hi-Fibre Orange

For oral use. Always take this medicine exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

Fill a glass with approximately 150ml cold water. Pour in the required amount (see dosage below). Stir well and drink straight away, preferably after meals.

Do not take without water. This product should be taken at least 30 mins before or after taking other medicines and should not be taken immediately before going to sleep.

Adults and children over 12 years: Take one sachet in the morning and one in the evening, preferably after meals

Children aged 6 to 12 years: Take half to one level 5 ml spoonful depending on size and age, morning and evening, preferably after meals.

Children under 6 years: Not recommended for children under 6 years of age.

If symptoms worsen or if there is no bowel movement after 3 days of treatment, consult a doctor.

If you take more Fybogel Hi-Fibre Orange than you should

Do not take more than directed. If you accidentally take more than you should, drink plenty of water.

If you forget to take Fybogel Hi-Fibre Orange

If a dose is missed, do not take a double dose; just carry on with the next recommended dose.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

This product can cause allergic reactions with symptoms including difficulty in breathing, wheezing or coughing, skin rash, itching and a sudden life-threatening allergic reaction.

This product contains allergens and it is possible to come into contact with them via skin, inhalation or when taking the product by mouth and may cause red or itchy eyes, runny or blocked nose and a skin rash. If symptoms appear, you should immediately stop using this product and contact your doctor or pharmacist. Due to the increased fibre intake of your diet you may experience wind (flatulence) or bloating during the first few days of taking this product, which should lessen as you continue to take it. If you have any other symptoms after taking this product, tell your doctor or pharmacist.

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 internet at 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 Fybogel Hi-Fibre Orange

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

Store below 30°C in a dry place. Do not use after the expiry date stated on the carton.

6. Contents of the pack and other information

What Fybogel Hi-Fibre Orange contains

Each single dose sachet contain 3.5 g Ispaghula Husk. Other ingredients are potassium bicarbonate, sodium bicarbonate, citric acid, riboflavin sodium phosphate, beta-carotene, aspartame (E951), orange flavour, saccharin sodium, polysorbate 80 and silica colloidal anhydrous.


Marketing Authorization Holder and Manufacturer

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