

PACKAGE LEAFLET: INFORMATION FOR THE USER

Fybogel Orange

3.5 g Granules

Ispaghula Husk

Read all this information because it contains important information for you.

This medicine is available without prescription. However, you still need to take Fybogel Orange carefully to get the best results from it.

Keep this leaflet. You may read it again

Ask your pharmacist if you need more information or advice.

You must contact your doctor if your symptoms worsen or do not improve.

If any side effects get serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Fybogel Orange is and what it is used for
2. Before you take Fybogel Orange
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1. WHAT FYBOGEL IS AND WHAT IS IT USED FOR

Fybogel Orange is a high fibre drink containing the active ingredient Ispaghula Husk. It increases fibre in your diet helping your digestive system work more efficiently and relieve constipation, helping to store and maintain regularity.

It should be used for patients requiring a high fibre regime for use in the relief of constipation.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE FYBOGEL ORANGE

Do not take Fybogel if:

- You are allergic to plantago ovata seeds or any of the other ingredients of this medicine (see in this section "Warnings and precautions" below)
- You are allergic to the active ingredient or any of the excipients listed in section 6
- You are suffering from blockage of the bowel (intestinal obstruction, faecal impaction)
- You are suffering from muscle 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 are suffering from phenylketonuria, contains aspartame (E951) a source of phenylalanine
- You have a sudden change in bowel habit that lasts more than 2 weeks
- You have undiagnosed rectal bleeding and are not able to defecate following the use of a laxative
- You have difficulty in swallowing or any throat problems

Warnings and precautions:

Talk to your doctor or pharmacist before taking Fybogel Orange:

If you experience allergic reactions from exposure to the product, exposure to the product should be stopped immediately.

If you are an individual with continued occupational contact to powder of Plantago ovata seeds (e.g. healthcare workers, caregivers) allergic sensitisation may occur due to inhalation. This can lead to hypersensitivity reactions.

If you have symptoms such as abdominal pain, nausea and vomiting as these symptoms can be signs of potential or existing intestinal blockage.

Taken any other medicines:

Ispaghula and other bulk-forming laxatives may delay or reduce the gastrointestinal absorption of other drugs such as cardiac glycosides, coumarin derivatives, lithium, or vitamins (such as vitamin B12) and minerals (such as calcium, iron, or zinc).

Diabetic patients should take Ispaghula husk under medical supervision because adjustment of anti-diabetic therapy may be necessary.

Patients taking thyroid hormones require medical supervision because the dose of the thyroid hormones may have to be adjusted.

Pregnancy and breast-feeding

Fybogel Orange may be used during pregnancy if necessary and if change of nutrition is not successful. Consult your doctor or pharmacist before using Fybogel Orange during pregnancy.

Important information about some of the ingredients of Fybogel Orange

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 ORANGE

Fill a glass with approximately 240ml (8 fluid ounces) of cold water. Pour the required granules (see dosage below). Stir well and drink immediately.

When preparing the product for administration it is important to try to avoid inhaling the powder. If there have been no bowel movements after 3 days of treatment, a doctor should be consulted. Fybogel Orange should be taken during the day at least ½ hour to 1 hour before or after taking other medicines and should not be taken immediately before going to sleep. The effects start 12-24 hours later.

Dosage:

ADULTS AND CHILDREN OVER 12: One sachet dissolved in 240ml (8 fluid ounces) of water each morning and evening, preferably after meals.

CHILDREN 6 to 12 YEARS: Half to one 5ml spoonful of granules dissolved in 240ml (8 fluid ounces) of water, depending on age and size, morning and evening.

CHILDREN UNDER 6 YEARS: The use in children is not recommended.

Do not take Fybogel Orange without water. Adequate fluid intake should be maintained.

If you take more Fybogel Orange than you should

Drink plenty of water. You may notice abdominal discomfort, flatulence, and attention should be paid to maintaining fluid intake, particularly if the granules have been taken without water contrary to dosage instructions. Consult your doctor if symptoms persist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Fybogel Orange can cause side effects, although not everybody gets them.

Flatulence and bloating may be expected during the first few days of treatment, but diminish during continued treatment. Abdominal distension and risk of intestinal or oesophageal obstruction and blockage of the bowel may occur. Skin conditions such as rash and itching have also been reported. The frequency is not known.

Plantago ovata seeds contain substances which may lead to allergic reactions after use of the product by the oral route, contact with the skin or, in case of powder formulations, also by inhalation.

The allergic symptoms may include running nose, redness of the eye, difficulty in breathing, skin reactions, itching, and in some cases anaphylaxis (a sudden, generalised allergic reaction that may lead to life-threatening shock). Individuals manipulating the powder formulations routinely are more prone to these reactions (see section 2).

In the event of an allergic reaction stop taking or preparing Fybogel Orange and seek advice from your doctor or pharmacist immediately.

If any of the side effects get serious, or if you notice any side effects not listed on this leaflet, please tell your doctor or pharmacist.

Reporting of side effects: If you get any side effects, talk to your doctor, pharmacist or nurse. You can report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie

5. HOW TO STORE FYBOGEL ORANGE

Keep out of the reach and sight of children.

Store below 30°C. Store in the original package to protect them from moisture. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicine if no longer required.

These measures will help to protect the environment. Do not use this medicine after the expiry date which is stated on the carton and sachet. The expiry date refers to the last day of that month.

6. FURTHER INFORMATION

What Fybogel Orange contains

Each single dose sachet contains 3.5g Ispaghula Husk as the active ingredient. The other ingredients are Potassium hydrogen carbonate, Sodium hydrogen carbonate, Citric acid anhydrous, beta carotene 10% CWS/S (E160a) (contains: Beta Carotene, All-rac-alpha-tocopherol, refined maize oil, maize starch and modified food starch) Riboflavin sodium phosphate, Aspartame (E951), Orange flavour, Saccharin Sodium, Silica colloidal anhydrous, and Polysorbate 80.

What Fybogel Orange looks like and content of the pack

Orange flavoured flaky granules of orange to buff colour which, when added to water forms a suspension.

Fybogel Orange is available in packs containing 10 or 30 sachets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and manufacturer

MA Holder: Reckitt Benckiser Ireland Ltd. 7 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

Manufacturers: Reckitt Benckiser Healthcare (UK) Ltd., Dansom Lane, Hull, HU8 7DS, UK and RB NL Brands B.V. Schiphol Blvd 207, 1118 BH Schiphol, NL

For product queries contact: 01 6305429

This leaflet was prepared: upon approval