

PACKAGE LEAFLET: INFORMATION FOR THE USER

Fybogel Orange

3.5 g Granules

Ispaghula Husk

Read all of 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 or nurse has told you.

Keep this leaflet. You may need to read it again

Ask your pharmacist if you need more information or advice.

If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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

What is in this leaflet:

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

1. WHAT FYBOGEL ORANGE 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 gently relieves constipation in a natural way, helping to restore and maintain regularity.

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

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

Do not take Fybogel Orange if:

- You are allergic to ispaghula husk or any of the other ingredients of this medicine (see section 6)
- You are suffering from blockage of the bowel (abnormal constrictions, intestinal obstruction, faecal impaction)
- You are suffering from muscle weakness of the bowel wall (colonic atony)
- You are suffering from expansion and/or dilation of the colon (mega-colon)
- You are suffering from drug-induced reduction of gut motility
- The speed in which material moves through your gut has always been slow (naturally occurring reduced gut motility)
- You have any disease affecting the oesophagus and/or the cardia (the first part of the stomach below the oesophagus)
- 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 are a healthcare worker or caregiver who has been preparing for administration products with powder of ispaghula husk to patients for a long time, you might have become allergic to these products due to continued inhalation of the powder. In case of symptoms (listed in section 4) are confirmed as allergic, do not use the product (see in this section, "Do not use").
- If you are suffering from phenylketonuria (contains aspartame (E951)) which is a source of phenylalanine
- If you have symptoms such as abdominal pain, nausea and vomiting as these symptoms can be signs of potential or existing intestinal blockage.
- This product should only be used together with other medicines known to cause constipation e.g. opioids (codeine, morphine) under strict medical supervision. If the peristaltic action of the gut is reduced, there is potential for intestinal obstruction or blockage.

Take special care:

- Use in children under 6 years of age is not recommended due to a lack of evidence to support its effective use.
- This product should not be taken dry and should always be taken mixed with fluid (8 fluid ounces or 240mL of water or other liquid per sachet). If taken without the correct amount of liquid, it can cause obstruction of the throat and food pipe with choking and intestinal obstruction, resulting in difficulty swallowing or breathing, chest pain & vomiting.
- Debilitated patients and/or elderly patients requires medical supervision.

If symptoms persist longer than 3 days, please consult your doctor.

Do not take immediately before going to sleep.

Other medicines and Fybogel Orange:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Ispaghula and other bulk-forming laxatives may delay or reduce the gastrointestinal absorption of other drugs such as cardiac glycosides (e.g. Digoxin), coumarin derivatives (e.g. warfarin or coumadin), anticonvulsants (e.g. carbamazepine), lithium, or vitamins (such as vitamin B12) and minerals (such as calcium, iron, or zinc). Because of this, Fybogel Orange should be taken ½ to 1 hour before or after taking other medicines.

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. You should not take this medicine if you are taking other medicines which may cause constipation (e.g. codeine or morphine) unless under medical supervision.

Pregnancy, breast-feeding and fertility

Consult your doctor or pharmacist before using Fybogel Orange during pregnancy.

Fybogel Orange may be used during pregnancy if necessary and if change of nutrition is not successful. Laxative bulk producers should be used before using purgatives.

Fybogel Orange may be used during breast-feeding.

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

For oral use. Fill a glass with approximately 240ml (8 fluid ounces) of cold water. Pour in the required amount of 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 under 6 years of age 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, intestinal obstruction and 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 of these side effects is not known.

Ispaghula husk 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 runny nose, redness of the eye, difficulty in breathing, skin reactions, itching, swelling 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 possible 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. This includes any possible side effects not listed in this leaflet. You can report side effects directly via HPRC Pharmacovigilance. Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE FYBOGEL ORANGE

Keep out of the sight and reach of children.

Store below 30°C. Store in the original package to protect them from moisture.

Do not use after the expiry date stated on the carton and sachets (EXP: month/year). The expiry date refers to the last day of that month.

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

6. CONTENTS OF THE PACK AND OTHER 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 (E954), Silica colloidal anhydrous, and Polysorbate 80.

What Fybogel Orange looks like and contents of the pack

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

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

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