130 mm

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PACKAGE LEAFLET: INFORMATION FOR THE USER

Fybogel Citrus

3.5g Granules

Ispaghula Husk

Read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription. However you still need to take Fybogel Citrus carefully to get the best results from it.
Keep this leaflet. You may need to read it again.
Ask your pharmacist if you need more information or advice.
You must contact a doctor if your symptoms worsen or do not improve.
If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Fybogel Citrus is and what is it used for
2. Before you take Fybogel Citrus
3. How to take Fybogel Citrus
4. Possible side effects
5. How to store Fybogel Citrus
6. Further information

1. WHAT FYBOGEL CITRUS IS AND WHAT IT IS USED FOR
Fybogel Citrus 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 regimen. It is also recommended to help maintain a normal bowel function among patients suffering from irritable bowel syndrome, colostomy or ileostomy, haemmorhoids (piles), anal fissure, persistent diarrhoea associated with diverticular disease or ulcerative colitis.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE FYBOGEL CITRUS
Do not use Fybogel Citrus 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)
- You are suffering from muscle weakness of the bowel wall (colonic atony)
- You suffer 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 Citrus:
if you are a healthcare worker or care giver who has been preparing for administration products with powder of plantago ovata seeds 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")

Taking other medicines:
Ispaghula and other bulk-forming laxatives may delay or reduce the absorption of other drugs, vitamins, or minerals. Consult a healthcare professional. Diabetic patients should take Ispaghula husk under medical supervision because adjustment of anti-diabetic therapy may be necessary.

Pregnancy and breast-feeding:
Fybogel Citrus 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 Citrus may be used during breast-feeding

Important information about some of the ingredients of Fybogel Citrus:
Fybogel Citrus contains Aspartame (E951) which is a source of phenylanaline. This may be harmful for patients with phenylketonuria.

3. HOW TO TAKE FYBOGEL CITRUS
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.

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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 Citrus should be taken during the day at least 1/2 hour to 1 hour before or after taking other medicines and should not be taken immediately before going to sleep.

Dosage:
ADULTS AND CHILDREN OVER 12: One sachets each morning and evening, preferably after meals.
CHILDREN 6 to 12 YEARS: Half to one level 5 ml spoonful, 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 Citrus without water. Adequate fluid intake should be maintained.

If you take more Fybogel Citrus 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 Citrus 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.
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 Citrus and seek advice from your doctor or pharmacist immediately.

If any of the side effects gets serious, or if you notice any side effects not listed in 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 also 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE FYBOGEL CITRUS
Keep out of the reach and sight of children.
Do not store above 30°C. Store in the original package in order to protect 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 medicines no longer required.
These measures will help to protect the environment.

6. FURTHER INFORMATION
Each single dose sachet contains 3.5g Isphagula 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, Maize oil refined, Maize Starch and Modified food starch), Riboflavin sodium phosphate, Aspartame (E951), Orange flavour, Saccharin sodium (E954), Silica colloidal anhydrous, Polysorbate 80.

What Fybogel Citrus looks like and contents of the pack
Fybogel Citrus are semi-transparent buff coloured granules with an odour of orange which when added to water form a suspension.
Available in a carton containing 2, 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.
Manufacturer: Reckitt Benckiser Healthcare (UK) Ltd., Dansom Lane, Hull, HU8 7DS, UK.

For product queries contact: 01 6305429
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Segment:	Powder
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Market/Country:	Ireland
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RBH Contact:	Jennifer Shannon

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Truncated By:	N/A
Full Height:	N/A
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BWR:	N/A
Encoded Data:	N/A

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