

PACKAGE LEAFLET: INFORMATION FOR THE USER

Fybogel Mebeverine

Granules for Oral Suspension

Ispaghula husk 3.5g

Mebeverine hydrochloride 135mg

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 a doctor if your symptoms worsen or do not improve.

What is in this leaflet:

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

1.WHAT FYBOGEL MEBEVERINE IS AND WHAT IT IS USED FOR

Fybogel Mebeverine contains ispaghula husk, which is a natural plant material which is high in fibre. Ispaghula husk increases fibre in your diet helping your digestive system work more efficiently and gently relieve constipation in a natural way helping to restore and maintain regularity. Mebeverine is an antispasmodic drug which relieves spasms and cramps, which occur in the gut causing pain.

This product is used to relieve symptoms of irritable bowel syndrome. If you have irritable bowel syndrome, you are likely to suffer from painful spasms of the gut and irregular bowel habits. Fybogel Mebeverine is effective in relaxing the spasms of the gut, relieving pain. At the same time Fybogel Mebeverine will help you to restore and maintain bowel regularity.

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

Do not take Fybogel Mebeverine if

- You are allergic to ispaghula husk or mebeverine or any of the other ingredients of this medicine (see section 6)
- You are suffering from a blockage of the bowel (abnormal constrictions, intestinal obstruction or faecal impaction)
- You have 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 mobility)
- You have difficulty in swallowing or any throat problems
- You have a sudden change in bowel habit that has persisted more than 2weeks
- You have undiagnosed rectal bleeding following the use of a laxative.
- You fail to pass a bowel motion following the use of a laxative
- You have paralytic ileus (suffer from any disorder affecting your gut nerves and muscles that can slow down gut motion)
- You have any disease affecting the oesophagus and/or the cardia (the first part of the stomach below the oesophagus)

Warnings and precautions:

Talk to your doctor or pharmacist before taking Fybogel Mebeverine:

- If you develop symptoms such as chest pain, fever, nausea, vomiting, difficulty in swallowing or breathing, changes in bowel movements, abdominal tenderness, bleeding from the bowel, loss of appetite or weight loss. Consult your doctor if your symptoms worsen, or if they do not improve after two weeks of treatment.
- 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.
- If this is the first time you have had these symptoms, consult your doctor before using Fybogel Mebeverine as it may not be the right treatment for you.
- If you are a health care worker or caregiver who has been preparing products with powder of ispaghula husk for patients for a long time, you might have become allergic to these products due to continued inhalation of the powder. If you experience allergy symptoms (listed in section 4), do not use the product (see in this section, "Do not take Fybogel Mebeverine if").
- 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:

- Fybogel Mebeverine should be used with care in patients with kidney or liver impairment, and those with heart disorders.
- Fybogel Mebeverine **is not recommended for children under 12 years**
- A change of diet should always be considered first in the management of irritable bowel syndrome. It is recommended that the use of a bulk laxative alone should be tried before using Fybogel Mebeverine.
- Always ensure that adequate fluid intake is maintained and that the product is always taken with fluid (approx. 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.
- Medical supervision is required for debilitated and/ or elderly patients when taking Fybogel Mebeverine.

Do not take this product immediately before sleep.

If symptoms persist longer than 2 weeks, please consult your doctor.

Other medicines and Fybogel Mebeverine

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

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.

This product may delay or reduce the absorption of other drugs such as blood thinning agents (e.g. warfarin or coumadin), some heart drugs (e.g. digoxin), anticonvulsants (e.g. carbamazepine), lithium, or vitamins (such as vitamin B12) and minerals (such as calcium, iron, or zinc). Because of this, Fybogel Mebeverine should be taken ½ to 1 hour before or after intake of other medicines.

If you are diabetic or taking thyroid hormones speak to your doctor before taking this product as you may need your dosage to be adjusted.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Fybogel Mebeverine should not be used during pregnancy unless considered essential by the physician.

Fybogel Mebeverine should not be used during breast-feeding.

Driving and using machines.

There are no known effects on driving and use of machines

Important information about some of the ingredients of Fybogel Mebeverine

This medicine contains 16 mg 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 58.65 mg sodium (main component of cooking/table salt) in each sachet. This is equivalent to 2.9% of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains 2.5 mmol (or 97.6 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 MEBEVERINE

Stir the contents of a sachet into a glass of cold water (approximately 240 ml minimum) and drink immediately. Fybogel Mebeverine must be taken with an adequate amount of liquid, as directed.

Blockage of the gut may occur if the granules are not prepared with enough liquid.

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

Dosage:

Adults and children over 12: should take Fybogel Mebeverine half an hour before a meal, one sachet in the morning and one in the evening, or as prescribed by your doctor. If necessary, an additional sachet may be taken before the midday meal.

Fybogel Mebeverine is not recommended for children under 12 years.

The last dose should not be taken immediately before going to sleep.

Effects may take several hours. When preparing the product for administration, it is important to try to avoid inhaling any of the powder in order to minimise the risk of sensitisation to the active ingredient.

If you miss a dose

Simply continue with your treatment when the next dose is due.

If you take more Fybogel Mebeverine than you should

Drink plenty of water. You may notice abdominal discomfort, intestinal obstruction and flatulence, and you may also experience nervous system or heart related effects. Attention should be paid to maintaining fluid intake, particularly if the granules have been taken without water contrary to dosage instructions. Contact your doctor or attend the nearest casualty department immediately.

4. POSSIBLE SIDE EFFECTS

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

Oesophageal obstruction, intestinal obstruction or faecal impaction may occur.

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 Mebeverine and seek advice from your doctor or pharmacist immediately. The frequency of the above side effects is not known.

Flatulence and bloating may be expected during the first few days of treatment but diminish during continued treatment.

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, 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 MEBEVERINE

Keep out of the sight and reach of children.

Do not store above 30°C. Store in the original package.

Do not use after the expiry date shown on the pack (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. CONTENTS OF THE PACK AND OTHER INFORMATION

What Fybogel Mebeverine contains

Each single dose of granules contains 3.5g Ispaghula Husk and 135mg Mebeverine Hydrochloride as the active ingredients.

The other ingredients are potassium hydrogen carbonate, sodium hydrogen carbonate, microcrystalline cellulose, basic butylated methacrylate copolymer, sterilised talc, macrogol, citric acid, polysorbate 80, silica colloidal anhydrous, saccharin sodium, aspartame E951, orange flavour, beta-carotene (E160a) 10% CWS/S (contains: Beta carotene, All-rac-alpha tocopherol, Maize oil refined, Maize Starch and Modified food starch), riboflavin sodium phosphate and apo-carotenal colouring

What Fybogel Mebeverine looks like and contents of the pack

Fybogel Mebeverine are buff coloured granules and orange coloured spheroids.

Available in a carton containing 2, or 10 sachets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

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

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

For product queries contact: 01 6305429

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This leaflet was last revised in: upon approval