

Fybogel Mebeverine

Ispaghula Husk
Mebeverine hydrochloride



PATIENT INFORMATION LEAFLET

Please read this leaflet carefully before taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you are not sure about anything, ask your doctor or pharmacist.
- **You must consult a doctor if you develop new symptoms, or if your symptoms worsen or do not improve after two weeks of treatment.**

WHAT IS FYBOGEL MEBEVERINE?

Fybogel Mebeverine contains ispaghula husk, a natural plant material which is high in fibre. It works by increasing the bulk of the contents of the gut passing through the digestive system, helping your body to work normally. Mebeverine is an antispasmodic drug which relieves spasms and cramps, which occur in the gut causing pain.

WHAT IS FYBOGEL MEBEVERINE USED FOR?

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

BEFORE TAKING FYBOGEL MEBEVERINE

Do not use Fybogel Mebeverine if you are allergic to ispaghula husk, mebeverine, or any of the other ingredients of this medicine (see in this section "Warnings and precautions" below)

Do not take Fybogel Mebeverine if your doctor has told you that you

- Are suffering from a **blockage of the bowel**
- **Have muscle weakness/ decreased activity of the bowel** (megacolon or paralysis of the intestine)
- **Do not take Fybogel Mebeverine if you**
 - have **difficulty swallowing and/or any throat problems.**
 - are suffering from **severe constipation** and/or have passed **blood from the bowel.**
 - have had a **sudden change in bowel habit** that has **persisted for more than 2 weeks.**
 - are **breastfeeding**

Blockage of the gut may occur if the granules are not prepared with enough liquid. Symptoms can be **chest pain, vomiting, or difficult swallowing and/or breathing.**

If this is the first time you have had these symptoms

Consult your doctor before using Fybogel Mebeverine, as this may not be the right treatment for you.

Warnings and precautions:

Check with your doctor before using Fybogel Mebeverine if you

- Are a **healthcare worker or care giver** who has been **preparing for administration** products with 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 "Possible side effects" below) are confirmed as allergic, do not use the product (see in this section, "Do not use" above).
- Have an inherited condition called **phenylketonuria**, because the product is sweetened with aspartame E951, which is a source of phenylalanine. This may be harmful for people with phenylketonuria.
- Are **aged 40 years or over** or **debilitated.**
- Have **abdominal pain** and/or you are **feeling sick or vomiting**
- Have **lost your appetite or lost weight**
- Are looking **pale and feeling tired**
- Have a **fever**
- Have recently **travelled abroad**
- Are or may be **pregnant**
- Have abnormal **vaginal bleeding or discharge**
- Have **difficulty or pain passing urine**
- Have been prescribed **diuretic medicine** or medicines that can cause **constipation**
- Have **acute porphyria** (metabolic disorder affecting the production of heme)
- Have problems with your **liver or kidneys.**
- Have heart or circulatory diseases.

Not recommended in children below 12 years.

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.

The medicinal product contains 2.56 mmol (or 58.65 mg) sodium (main component of cooking/table salt) per sachet. This is equivalent to 2.9% of the recommended maximum daily dietary intake of sodium for an adult. To be taken into consideration by patients on a controlled sodium diet. 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.

Talk to your doctor if you get new symptoms, your symptoms get worse or if they do not improve after 2 weeks of treatment.

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Pharmacode Reads This Way
First Bar Last Bar



Other medicines and Fybogel Mebeverine:

Do not take Fybogel Mebeverine within 1/2 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 Mebeverine with meals.
- medicines for thyroid problems - your doctor may need to change the dose of the thyroid hormones you are taking.

HOW SHOULD I TAKE FYBOGEL MEBEVERINE?

Stir the contents of a sachet into a glass of cold water (at least 150 ml) and drink immediately.

Fybogel Mebeverine must be taken with an adequate amount of liquid, as directed. **Do not take Fybogel Mebeverine without water, immediately before going to bed, or 1/2 to 1 hour before or after taking any other medicines.**

Effects may take 12-24 hours.

When preparing the product for administration, it is important to try to avoid inhaling the powder.

The product is intended for oral administration as a suspension in water.

Dosage: Adults, the elderly and children aged 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 should not be taken by children **12 years and under.**

Length of treatment

Consult a doctor if you develop new symptoms or if your symptoms worsen or do not improve after two weeks of treatment.

If you miss a dose, continue with your treatment when the next dose is due.

If you take more Fybogel Mebeverine than you should, drink plenty of water.

The product should be taken at doses as per the directions, in short term use. In the treatment of chronic conditions, under long-term treatment, additional adverse effects may occur.

POSSIBLE SIDE EFFECTS

You may experience allergic skin reaction including skin rash with itching e.g. "hives" or "nettle rash". If you start to itch or get rash, STOP taking Fybogel Mebeverine and tell your doctor at once.

Hypersensitivity or severe allergic reaction including swollen face or breathing problems. Tell your doctor straight away if you notice any of these symptoms and STOP taking Fybogel Mebeverine. Ispaghula husk contains 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 swelling of the face, lips, tongue, and other parts of the body, blocked or 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 "Before taking Fybogel Mebeverine" above).

You may experience flatulence or bloating for the first few days after starting this medicine, but these effects should lessen as you continue treatment.

You may experience difficulty swallowing and/or blockage of the bowel, especially if swallowed with insufficient water. To decrease the risk of stomach or intestine blockage, the product should **only be used** together with medicinal products (e.g. opioids, opioid-like agents and loperamide) known to inhibit peristaltic movement (contractions that move food through the digestive tract) **under medical supervision.**

The frequency of these side effects is unknown.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard, or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

HOW TO STORE

Keep out of the sight and reach of children. Do not use after the expiry date shown on the pack (EXP month/year). Store below 30°C. Store in the original package to protect from moisture.

FURTHER INFORMATION

Each single dose of **Fybogel Mebeverine contains:**

- 3.5g ispaghula husk and 135mg mebeverine hydrochloride. These are the active ingredients (which make the product work).
- Potassium hydrogen carbonate, sodium hydrogen carbonate, microcrystalline cellulose, basic butylated methacrylate copolymer, sterilised talc, polyethylene glycol 6000, citric acid, polysorbate 80, silica colloidal anhydrous, saccharin sodium, aspartame E951, orange flavour, beta-carotene, riboflavin sodium phosphate and apo-carotenal colouring.

What Fybogel Mebeverine looks like and contents of the pack Fybogel Mebeverine comes in a carton containing ten sachets of orange flavoured granules.

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Manufacturer and PL Holder: Reckitt Benckiser Healthcare (UK) Limited, Hull, HU8 7DS, UK.

Manufacturer: RB NL Brands B.V. WTC Schiphol Airport, Schiphol Boulevard 207, 1118 BH

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Marketing Authorisation number: PL 00063/0025

Leaflet last revised August 2025.

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Guides 2 (if applicable)