

130 mm

APPROVED

By dodds at 3:17 pm, Jan 10, 2012

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, which is 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. 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.

BEFORE TAKING FYBOGEL MEBEVERINE

- Do not take Fybogel Mebeverine if your doctor has told you that you**
- are suffering from a **blockage of the bowel** (intestinal obstruction or faecal impaction)
 - have **decreased activity of the bowel** known as paralytic ileus
 - have **muscle weakness of the bowel wall** (colonic atony)
 - 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 **allergic** to any of the ingredients (see over page).

Fybogel Mebeverine **should not be taken by children under 12 years.**

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.

Check with your doctor before taking Fybogel Mebeverine if you

- are aged **40 years or over**
- have passed **blood from the bowel**
- are feeling **sick or vomiting**
- have **lost your appetite or lost weight**
- are looking **pale and feeling tired**
- are suffering from **severe constipation**
- 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**
- are on a **controlled sodium or potassium diet** (as each sachet contains 2.37mmol of sodium and 2.50 mmol of potassium).
- Have **acute porphyria** (metabolic disorder affecting the production of heme)

RB004777

HOW SHOULD I TAKE FYBOGEL MEBEVERINE?

Stir the contents of a sachet into a glass of cold water (approximately 1/4 pint or 150ml) 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.**

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 should not be taken by children *under 12 years.*

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

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

If you take more than you should

If you have taken too much Fybogel Mebeverine, drink plenty of water.

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.

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

If you have any other unwanted side effects after taking this product, tell your doctor or pharmacist.

HOW TO STORE

Keep out of the reach and sight 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

What Fybogel Mebeverine contains

Each single dose of granules contains

- 3.5 g ispaghula husk and 135 mg 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 and beta-carotene, riboflavine 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.

Fybogel and  are trademarks.

Manufacturer and Product Licence Holder in the UK:
Reckitt Benckiser Healthcare (UK) Limited, Hull, HU8 7DS, UK.
Leaflet last revised December 2011.

RB004777

RBH Artwork and Print Specification

Trident Reference No: TR535367
Action / Version: A
Brand: Fybogel
Brand Platform: Fibre Regularity
Sub Platform: Fybogel
Sub Brand: Mebeverine
Format: Powder
Delivery: Sachet
Pack Size: 10
Country: UK
Date Created: 22/12/11
Date Modified: 22/12/11

RBH Contact: Samantha Bradley

Artwork Type: Submission Only

Component Code (2D if applicable): RB004777
Parent Technical Packaging Specification: N/A

Bulk Code (if applicable): N/A
XXXX

CAD Cam Ref: Fyb-Lft-D0268244-130x255mm
Printer: Contego Packaging (Bradford, UK) Nampak
Substrate: Paper - White

Edgemark Position: N/A
Pharmacode No/NE: N/A



Print and Technical Colours



COLOURS TO MATCH RECOGNISED STANDARDS

BARCODE INFO

Barcode Type: Not Known
Barcode Number: N/A
Magnification: N/A
BWR: N/A
Truncated by (smallest Bar): N/A
Encoded Data: N/A

All other aspects of the bar code to conform to the current GS1 Operating Manual or other agreed commercial standard.



TRIDENT

Connaught House, Connaught Road,
Kingswood Business Park, Hull, HU7 3AP, England.
T: +44 (0) 1482 828100

Please note that any low resolution paper Canon colour copies associated with this job should be referred to for content, layout and colour separation only.

STUDIO USE ONLY Rebecca Milner v1.0
Sm*Art check results: G=0; 0=0; R=0; - RM - 22/12/11 14:29:43

ARTWORK APPROVAL

Approved by Sonoco Trident on behalf of Reckitt Benckiser

Signed: _____

Date: _____

UNDER NO CIRCUMSTANCES SHOULD THIS ARTWORK BE ALTERED WITHOUT PRIOR PERMISSION FROM TRIDENT.
Tel. Alan Smith: +44 (0)1482 710304

NOT APPROVED FOR COLOUR

CUSTOMER INFO:
Minimum Point Size = 9 pt

255 mm

Pharmacode Reads This Way
First Bar
Last Bar



Pharmacode Reads This Way
First Bar
Last Bar

290
280
270
260
250
240
230
220
210
200
190
180
170
160
150
140
130
120
110
100
90
80
70
60
50
40
30
20
10
mm