SCHEDULING STATUS:

S0

PROPRIETARY NAME AND DOSAGE FORM:

FYBOGEL® ORANGE Powder

COMPOSITION:

Each sachet of FYBOGEL ORANGE powder contains 3, 5 g of Ispaghula husk

Other ingredients include:

Citric acid anhydrous, potassium bicarbonate, sodium bicarbonate, orange flavor,

beta-carotene, riboflavin sodium phosphate, polysorbate 80

& silica colloidal (anhydrous)

Contains sweeteners (aspartame 0,016 g and saccharin sodium 0,012 g per sachet)

PHARMACOLOGICAL CLASSIFICATION:

A 11.5 Laxatives. Medicines acting on gastro-intestinal tract

PHARMACOLOGICAL ACTION:

Fybogel acts as a laxative agent because Ispaghula Husk absorbs and expands to give a mechanical laxative action and increases the rate of colonic transit.

INDICATIONS:

Fybogel is recommended for the treatment of patients requiring a high-fibre regimen, for constipation and for those requiring normalisation of faecal consistency as an irritable bowel syndrome and diverticular disease.

CONTRA-INDICATIONS:

- Hypersensitivity to Ispaghula or to any of the ingredient in FYBOGEL ORANGE.
- Patients on a salt restricted diet.

- Patients with suspected intestinal /bowel obstruction irrespective of the cause.
- Dysfunctional gut motility irrespective of the cause.
- Undiagnosed rectal bleeding and failure to defecate following the use of a laxative.
- Patients suffering from abnormal constrictions in the gastro-intestinal tract, with diseases of the oesophagus and cardia, intestinal obstruction, faecal impaction, Natural or drug induced reduction of gut motility and colonic atony such as senile mega-colon.
- Due to its aspartame content FYBOGEL ORANGE should not be given to patients with phenylketonuria.
- Patients with faecal impaction and symptoms such as abdominal pain, nausea and vomiting.

WARNINGS AND SPECIAL PRECAUTIONS:

Use with caution in patients with:

- Difficulty in swallowing.
- Intestinal narrowing decreased intestinal motility and, in the elderly, or debilitated patient as rare instances of gastrointestinal obstruction have been reported, especially when these medicines are taken with insufficient liquid.

Use is not recommended in children below 6 years of age due to insufficient data on efficacy. Laxative bulk producers should be used before using other purgatives if change of nutrition is not successful.

FYBOGEL ORANGE should not be taken dry and should always be taken mixed with fluid (8 fluid ounces or 240 mL of water or other liquid per sachet).

When taken with inadequate fluid amounts, bulk forming medicines can cause obstruction of the throat and oesophagus with choking and intestinal obstruction. Symptoms can be chest pain, vomiting, or difficulty in swallowing or breathing

If abdominal pain occurs or in cases of any irregularity of faeces, the use of FYBOGEL ORANGE should be discontinued, and medical advice must be sought after one week.

The treatment of debilitated patients and / or elderly patients requires medical supervision.

FYBOGEL ORANGE should not be used together with medicines known to inhibit peristaltic movement (e.g. opioids)

If symptoms persist longer than 3 days, the patient should consult a doctor.

Persistent constipation should be investigated. The habitual use of laxatives should be avoided. FYBOGEL ORANGE should be taken with adequate liquid to prevent faecal impactation and oesophageal obstruction. Rectal bleeding or failure to have a bowel movement after use of a laxative may indicate a serious condition. Discontinue use and consult a doctor. Hypersensitivity reactions have rarely been reported. Symptoms include rhinitis, urticaria, bronchospasm and anaphylactic shock.

Hypersensitivity

ISPAGHULA husk contains potent allergens.

Exposure to these allergens is possible through oral administration, contact with the skin and, in the case of powder formulations, also by inhalation. As a consequence, to this allergic potential, individuals exposed to FYBOGEL ORANGE can develop hypersensitivity reactions such as rhinitis, conjunctivitis, bronchospasm and in some cases, anaphylaxis. Cutaneous symptoms such as exanthema and/or pruritus have also been reported.

Effects on driving and using machinery

No effect on ability to drive and use machines

INTERACTIONS

FYBOGEL ORANGE and other bulk-forming laxatives may delay or reduce the gastrointestinal absorption of other medicines such as cardiac glycosides, **Warfarin**, lithium, or vitamins (such as vitamin B12) and minerals such as calcium, iron, or zinc). For this reason FYBOGEL ORANGE should not be taken ½ to 1 hour before or after intake of other medicines.

Diabetic patients should take ispaghula husk only under medical supervision because adjustment of anti-diabetic therapy may be necessary.

Use of ISPAGHULA husk concomitantly with thyroid hormones requires medical supervision because the dose of the thyroid hormones may have to be adjusted.

HUMAN REPRODUCTION

Safety and efficacy in pregnancy and lactation has not been established

DOSAGE AND DIRECTIONS FOR USE:

Oral administration:

FYBOGEL ORANGE should not be taken dry and should always be taken mixed with fluid (8 fluid ounces or 240 mL of water or other liquid per sachet).

Adults and children over 12: One sachet stirred into a full glass of water taken in the morning and evening.

Elderly:

Children 6 to 12 years : ½ - 1 level 5 ml medicine measure (depending on age and size) stirred into a full glass of water taken morning and evening

The use in children under 6 years of age is not recommended (See warnings and special precautions).

FYBOGEL ORANGE should be taken during the day at least ½ to 1 hour before or after intake of other medicines and should not be taken immediately before going to sleep.

FYBOGEL ORANGE is intended for oral administration as a suspension in a full glass of water (See warnings and special precautions) FYBOGEL ORANGE should be stirred into a glass of water and taken as soon as possible, preferably after meals.

The effects start 12-24 hours later

If there have been no bowel movements after 3 days of treatment a doctor should be consulted. (See special warnings and special precautions)

When preparing FYBOGEL ORANGE for administration, it is important to try

to avoid inhaling any of the powder in order to minimize the risk of sensitisation to the active ingredient.

SIDE EFFECTS:

More frequent:

Gastrointestinal disorders: Flatulence, abdominal distension. Oesophageal or intestinal obstruction or faecal impaction have been reported

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Symptoms of overdose:

In overdose, side effects will be exacerbated and exaggerated (SEE SIDE EFFECTS)

Abdominal discomfort, flatulence.

Treatment:

Treatment is symptomatic and supportive. An adequate fluid intake should be maintained, particularly if the granules have been taken without water.

In the event of overdosage, conservative measures should be taken. The patient may notice abdominal discomfort and flatulence and attention should be paid to maintaining an adequate fluid intake, (particularly if the powder has been taken without water, contrary to the administration instructions.)

IDENTIFICATION:

Buff, semi-transparent granules with an orangeodour.

PRESENTATION:

Cartons with 10 and 30 sachets. Each sachet contains 4,377 g of FYBOGEL ORANGE

STORAGE INSTRUCTIONS:

Store below 25 °C in a dry place. Keep out of reach of children.

REGISTRATION NUMBER:

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

© Reckitt Benckiser Pharmaceuticals (Pty) Limited,

8 Jet Park Road

Elandsfontein

1601

DATE OF PUBLICATION OF THIS PROFESSIONAL INFORMATION:

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