1.3.1.1 Professional Information for medicines for human use

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

AGIOBULK®

3,25 /0,11 g granules

2 QUALITIVE AND QUANTITIVE COMPOSITION

5 g of granules contains:

Seeds of Plantago ovata	3,25 g
Ispaghula husk	0,11 g

Contains sucrose: 5 g contains approximately 0,9 g sucrose or 0,07 bread units.

For full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Granules

Small grain, yellow-brown granules with an aromatic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For normalising and regulating bowel function under the following conditions:

- constipation and sluggishness of the bowel e.g. in bedridden patients, post-operatively, in pregnancy and in cases of haemorrhoids.
- diarrhoea or tendency to diarrhoeal stools to bring about less watery stools.

- alternating diarrhoea and constipation e.g. in patients with irritable bowel syndrome (IBS) and diverticulosis.

Note: Persistent irregularities of the bowels (more than 3 days) requires diagnosis by a medical practitioner.

4.2 Posology and method of administration

Posology

5 g granules = 7 ml = approximately 1 heaped 5 ml medicine measure.

Unless otherwise directed by the medical practitioner, the following dosages are recommended:

Adults:

Constipation: 10 g Agiobulk® should be taken after the evening meal (at least 1 hour before bedtime). If required, 5 g Agiobulk® may also be taken in the morning before breakfast.

Diarrhoea: initially take 10 g Agiobulk® 3 times daily (for 1 to 3 days) then, if required, 5 g Agiobulk® 3 times daily.

Irritable Bowel Syndrome (IBS) and diverticulosis: the dosage should be individualised – according to the medical practitioner's recommendations.

Special populations

Paediatric patients under the age of 12:

Half the adult dosage should be taken.

Method of administration

For oral use.

The granules should be swallowed with a full glass of liquid (preferably water). The granules should not be chewed or dissolved but swallowed whole.

One glass of water (200 ml) should be taken separately for every measuring spoon and wait at least 5 minutes before taking another measuring spoon.

An interval of ½ to 1 hour should be adhered to after the intake of other medicines.

The daily consumption of fluid should be 1 - 2 litres.

4.3 Contraindications

- Hypersensitivity to the active substances (seeds of plantago ovata and ispaghula husk), peppermint oil or to any of the other excipients listed in section 6.1.
- Agiobulk® should not be given to patients with unexplained abdominal pain or with symptoms or signs of ileus or megacolon syndrome; stenosis and obstruction within the gastrointestinal tract including the oesophagus and in patients who have difficulty in swallowing or have throat problems.
- Agiobulk® should not be used by patients: with faecal impaction (faecal stones); after intake of a laxative not followed by defecation and with rectal bleeding not further investigated.
- Agiobulk® should not be used by patients with poorly controlled diabetes.

4.4 Special warnings and precautions for use

In cases of diarrhoea, where there is no response to Agiobulk®, a medical practitioner should be consulted and electrolyte levels (especially that of potassium) should be checked.

Agiobulk® should not be used if there is abdominal pain, nausea and/or vomiting.

If a change in bowel habit occurs and persists for more than 2 weeks, a medical practitioner should be consulted to determine the cause.

Inadequate fluid intake may cause obstruction of the bowel. Agiobulk® must be taken with adequate liquid (200 ml of water for every measuring spoon) to prevent faecal impaction and oesophageal obstruction.

Not to be used by patients with faecal impaction and symptoms such as abdominal pain, nausea and vomiting unless advised by a medical practitioner because these symptoms can be signs of potential or existing obstruction.

If the constipation does not resolve within 3 days, if abdominal pain should occur or in case of irregular bowel movement, use of Agiobulk® should be discontinued and a medical practitioner should be consulted.

Treatment of debilitated patients and the elderly must occur under the supervision of a medical practitioner.

Excipient information

Sucrose

Agiobulk® contains sucrose (0,9 g per measuring spoon or 0,07 bread units) which may have an effect on the glycaemic control of patients with diabetes mellitus.
Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take Agiobulk®.

4.5 Interaction with other medicines and other forms of interaction

Bulk-forming laxatives, including Agiobulk®, lower the transit time through the gut and could interfere with the absorption of other medicines such as minerals (e.g. calcium, iron, lithium, zinc), vitamins (vitamin B12), cardiac glycosides and coumarins. Therefore, an interval of ½ to 1 hour should be adhered to before and after intake of other medicines.

Bulking-forming medicines and anti-diarrhoeal medicines, which inhibit motility (e.g. diphenoxylate, difenoxin, opium tincture, loperamide HCl), must not be administered simultaneously, because ileus can occur.

If thyroid hormones are taken concomitantly, dose adjustment could be necessary.

Note: In insulin dependent diabetics, a reduction in the insulin dose may be required.

4.6 Fertility, pregnancy and lactation

Women of childbearing potential/Contraception in males and females

No information available.

Pregnancy and Breastfeeding

There is no data available for the use of ispaghula husk during pregnancy and lactation.

Bulk-forming laxatives appear to be safe in pregnancy.

Fertility

No effect on fertility expected.

4.7 Effects on ability to drive and use machines

Agiobulk® has no known effect on mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision.

4.8 Undesirable effects

Tabulated list of adverse reactions

Immune system disorders	
Frequency unknown:	Plantago ovata and ispaghula husks/seeds contain allergic substances. Therefore, upon oral administration or upon skin contact, Agiobulk® may cause hypersensitivity reactions such as

	rhinitis, conjunctivitis and bronchospasm including anaphylactic reactions. Cutaneous symptoms including exanthema and/or pruritis have also been reported. Note: In sensitised patients, peppermint oil can cause hypersensitivity reactions (including respiratory distress).
Gastrointestinal disorders	
Frequency unknown:	Pre-existing complaints such as bloating or sensation of fullness may become more pronounced during the first days of treatment but will diminish as treatment is continued. In particular, in case of insufficient fluid intake, swelling of the abdomen (tympanites) may occur, and there will be a risk of ileus, oesophageal obstruction as well as constipation. Nausea and vomiting can occur. Water and electrolyte output may be increased due to the diarrhoea. In patients with ileostomy there is a danger of exacerbating water and electrolyte depletion.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications:

https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8).

Plenty of liquid should be drunk.

Treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 11.5 Laxatives

Pharmacotherapeutic group: Bulk-forming laxatives, ATC code: A06AC51.

Plantago ovata is a bulk-forming agent of plant origin. Plantago ovata and ispaghula husk's mode of action are due to their bulk-forming and swelling properties.

Regulates disturbed intestinal function in the following way:

a) Softening of hard stools:

Binding of part of the physiological fluids in the gastrointestinal tract prevents excessive re-absorption of water in the colon. The stool volume is increased, peristaltic activity stimulated, and the passage of intestinal contents shortened.

b) Solidification of watery stools:

The swelling agents bind excessive quantities of fluid, thus increasing the viscosity and volume of intestinal contents and lengthening the transit time.

5.2 Pharmacokinetic properties

Ispaghula husk is rich in alimentary fibres and mucilage and is capable of absorbing up to 40 times its own weight in water. Gut motility and transit rate can be modified by the pharmacological effects of ispaghula husk through mechanical stimulation of the gut wall as a result of the increase in intestinal bulk by water and a decrease in viscosity of the luminal contents.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

acacia,

caraway oil,

iron oxide red (E 172),

iron oxide yellow (E 172),

hard paraffin,

liquid paraffin,

peppermint oil,

sage oil,

sucrose,

talc,

titanium dioxide (E 171)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store at or below 25 ºC.

Keep container tightly closed.

6.5 Nature and contents of container

Container (inner lacquer PET-based) with inner lid (PP) and screw lid (PP) for

250 g granules (country specific).

Packs of 250 g.

6.6 Special precautions for disposal

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

Viatris South Africa (Pty) Ltd

4 Brewery Street

Isando, Johannesburg

1609

8 REGISTRATION NUMBER(S)

Q/11.5/303

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02 March 2012

10 DATE OF REVISION OF THE TEXT

23 April 2024

Namibia: 90/11.5/00507