PROFESSIONAL INFORMATION

Agiobulk®

SCHEDULING STATUS S0

PROPRIETARY NAME AND DOSAGE FORM
Agiobulk® granules

COMPOSITION
5 g of granules contains

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

Inactive ingredients include:
Talc, acacia, ferric oxides, paraffin, aromatics
Contains sugar: sucrose (approx. 0,9 g equivalent to 0,07 bread units).

PHARMACOLOGICAL CLASSIFICATION
A 11.5 Laxatives

PHARMACOLOGICAL ACTION
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 properties. Ispaghula husk is rich in alimentary fibers 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. Ispagula husk's anti-diarrhoeal effects are attributed to its ability to absorb water and convert fluid in the intestine into a more viscous mass and to prolong transit time of the intestinal contents.

INDICATIONS
For normalizing 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.

CONTRAINDICATIONS.
Agiobulk® should not be given to patients with unexplained abdominal pain or with symptoms or signs of ileus, 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 poorly controlled diabetes.

Hypersensitivity to the ingredients.

WARNINGS
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 two weeks, a medical practitioner should be consulted to determine the cause.

Inadequate fluid intake may cause obstruction of the bowel.

Contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucraseisomaltase insufficiency should not take **Agiobulk®**.
Contains sucrose which may have an effect on the glycaemic control of patients with diabetes mellitus.

INTERACTIONS
Bulk laxatives, including **Agiobulk®**, lower the transit time through the gut and could interfere Bulking agents and anti-diarrhoeal agents, which inhibit bowel motility (e.g. diphenoxylate, difenoxin, opium tincture, loperamide HCl), must not be administered simultaneously, because ileus can occur.

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

PREGNANCY AND LACTATION
There is no data available for the use of ispaghula husk during pregnancy and lactation. Bulk-forming laxatives appear to be safe in pregnancy.

DOSAGE AND DIRECTIONS FOR 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.

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 one hour before bedtime). If required, 5 g **Agiobulk®** may also be taken in the morning before breakfast.

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

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

Children under the age of 12 years:
Half the adult dosage should be taken.

Note for diabetics:
5 g **Agiobulk®** contains approximately 0,9 g sucrose, or 0,07 bread units.

SIDE EFFECTS AND SPECIAL PRECAUTIONS
Side effects
Flatulence and a sensation of fullness may be enhanced.
Water and electrolyte output may be increased due to the diarrheoa. In patients with ileostomy there is a danger of exacerbating water and electrolyte depletion.

Special Precautions
Agiobulk® must be taken with adequate liquid 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 doctor because these symptoms can be signs of potential or existing obstruction.

KNOWN SYMPTOMS OF OVER-DOSAGE AND PARTICULARS OF ITS TREATMENT
(See **SIDE EFFECTS AND SPECIAL PRECAUTIONS)**

Treatment is symptomatic and supportive.

IDENTIFICATION
Small grain, yellow –brown granules with an aromatic odour.

PRESENTATION
Containers of 250 g

STORAGE INSTRUCTIONS
Store at or below 30 °C. Keep container tightly closed.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER
Q/11.5/303

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
XIXIA PHARMACEUTICALS (PTY) LTD
4 Brewery Street, Isando, Kempton Park, 1600
Republic of South Africa

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Mylan

VOUBILJET

AGIOBULK®

SKEDULERINGSTATUS S0

EIENDOMSNAAM EN DOSEERVORM
Agiobulk® korrels

SAMESTELLING
5 g korrels bevat:

Sade van Plantago ovata	3,25 g
Ispaghula doppe	0,11 g

Onaktiewe bestanddele sluit in:
Talk, akasia, ysteroksides, paraffien, aromatiese middels.
Bevat suiker: sukrose (ongeveer 0,9 g ekwivalent aan 0,07 broodeenhede).

FARMAKOLOGIESE KLASSIFIKASIE
A 11.5 Lakseermiddels

FARMAKOLOGIESE WERKING
Plantago ovata is 'n massavormende middel van plantaardige oorsprong. Die werkingsmetode van Plantago ovata en Ispaghula doppe is as gevolg van hul massavormende eienskappe. Ispaghula doppe is ryk aan alimentêre vesels en mucilago en is in staat om tot 40 keer sy eie gewig aan water te absorbeer. Dermmotiliteit en vervoertyd kan deur die farmakologiese effekte van Ispaghula doppe gemodifiseer word deur meganiese stimulasie van die dermwand (as gevolg van 'n toename in intestinale vulstof veroorsaak deur water) en 'n afname in die viskositeit van die lumeninhoud. Die antidiarree-effekte van Ispaghula doppe word toegeskryf aan hul vermoë om water te absorbeer en vloeistof in die derm om te sit in 'n meer klewerige massa en om die vervoertyd van die derminhoud te verleng.

INDIKASIES
Om dermfunksie te normaliseer en te reguleer in die volgende toestande:
- hardlywigheid en traagheid van die derm, bv. in bedlêende pasiënte, post-operatief, in swangerskap en in gevalle van aambeie.
- diarree of 'n neiging tot diarree-stoelgang om minder waterige stoelgang te bewerkstellig
- afwisselende diarree en hardlywigheid, bv. by pasiënte met prikkelbare dermsindroom (PDS) en divertikulose.

KONTRA-INDIKASIES
Agiobulk® behoort nie vir pasiënte met onverklaarde abdominale pyn of met simptome of tekens van ileus, stenose en obstruksie binne die spysverteringskanaal insluitend die esofagus, en vir pasiënte wat probleme met sluk, of keelprobleme het, gegee te word nie.

Agiobulk® behoort nie deur pasiënte met swak beheerde diabetes gebruik te word nie.

Hipersensitiwiteit teenoor die bestanddele.

WAARSKUWINGS
In gevalle van diarree, waar daar geen respons op **Agiobulk®** is nie, behoort 'n mediese praktisyn geraadpleeg te word en elektrolietvlakke (veral dié van kalium) behoort nagegaan te word.
Agiobulk® behoort nie gebruik te word indien daar abdominale pyn, naarheid en/of braking teenwoordig is nie.

Indien 'n verandering in ontlasting voorkom en vir langer as twee weke aanhou, behoort 'n mediese praktisyn geraadpleeg te word om die oorsaak vas te stel.

Onvoldoende vloeistofinname mag obstruksie van die derm veroorsaak.

Bevat sukrose. Pasiënte met seldsame oorerflike probleme soos fruktose intoleransie, glukose-galaktose wanabsorpsie of sukrase-isomaltase ontoereikendheid, moet nie **Agiobulk®** neem nie.

Bevat sukrose, wat 'n effek mag hê op die glisemiese beheer van pasiënte met diabetes mellitus.

INTERAKSIES
Vulstof-bevattende lakseermiddels, insluitend **Agiobulk®**, verkort die vervoertyd deur die derm en kan moontlik inmeng met die absorpsie van ander stowwe. 'n Tussenpose van 'n ½ tot 1 uur voor en na inname van ander medikasies behoort nagekom te word .

Vulstof-bevattende middels en antidiarreemiddels, wat die motiliteit van die derm inhibeer (bv. difenoksilaat, difenoksien, opiumtinktuur, loperamied HCl), moet nie gelyktydig toegedien word nie omdat ileus kan voorkom.

Nota: By insulien-afhanklike diabete mag dit nodig wees om die insuliendosis te verminder.

SWANGERSKAP EN LAKTASIE
Daar is geen data aangaande die gebruik van Ispaghula doppe tydens swangerskap en laktasie beskikbaar nie. Dit wil voorkom dat massavormende lakseermiddels tydens swangerskap veilig is.

DOSIS EN GEBRUIKSAANWYSINGS
Die korrels behoort met 'n vol glas vloeistof (verkieslik water) ingesluk te word.
Die korrels behoort heel ingesluk te word en nie gekou of opgelos nie.

5 g korrels = 7 ml = ongeveer 1 opgehoopte 5 ml medisynemaat.

Tensy andersins deur die mediese praktisyn voorgeskryf, word die volgende dosisse aanbeveel:

Volwassenes:
Hardlywigheid: 10 g **Agiobulk®** behoort na aandete (ten minste een uur voor slapenstyd) geneem te word. Indien nodig, kan 5 g **Agiobulk®** ook in die oggend voor ontbyt geneem word.
Diarree: neem aanvanklik 10 g **Agiobulk®** drie keer daagliks (vir 1 tot 3 dae), dan indien nodig, 5 g **Agiobulk®** drie keer daagliks.

Prikkelbare Dermsindroom (PDS) en divertikulose: die dosis behoort individueel aangepas te word volgens die aanbeveling van 'n mediese praktisyn.

Kinders onder die ouderdom van 12 jaar:
Helfte van die volwasse dosis behoort geneem te word

Nota vir diabete:
5 g **Agiobulk®** bevat ongeveer 0,9 g sukrose, of 0,07 broodeenhede.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS
Newe-effekte
Winde en 'n sensasie van volheid mag versterk word.
Water- en elektrolietuitskeiding mag met diarree verhoog. By pasiënte met ileostomie bestaan daar die gevaar dat water- en elektrolietuitputting vererger kan word.

Spesiale Voorsorgmaatreëls
Agiobulk® moet met genoegsame vloeistof geneem te word om fekale impaksie en esofageale obstruksie te voorkom.

Moet nie deur pasiënte met fekale impaksie en simptome soos abdominale pyn, naarheid en braking gebruik word nie, tensy dit deur 'n mediese praktisyn aanbeveel word, omdat hierdie simptome tekens van potensiële of bestaande obstruksie kan wees.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN
(Sien **NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS)**

Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE
Klein gekorrelde, geel-bruin korrels met 'n aromatiese geur.

AANBIEDING
Houers van 250 g

BEWARINGSINSTRUKSIES
Bewaar teen of benede30 °C. Die houer moet dig gesluit gehou word.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER
Q/11.5/303

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