

HCR: Viatrix South Africa (Pty) Ltd

AGIOBULK®

Each 5 g granules contain 0,11 g ispaghula husk & 3,25 g seeds of plantago ovata

1.3.2 Patient Information Leaflet

SCHEDULING STATUS

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AGIOBULK®

3,25 /0,11 g granules

Seeds of Plantago ovata and Ispaghula husk

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

Read all of this leaflet carefully because it contains important information for you

Agiobulk® is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use Agiobulk® carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Agiobulk® with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What Agiobulk® is and what it is used for.
2. What you need to know before you take Agiobulk®.
3. How to take Agiobulk®.
4. Possible side effects.
5. How to store Agiobulk®.
6. Contents of the pack and other information.

1. What AGIOBULK® is and what it is used for

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Agiobulk® is a bulk-forming laxative and it is used for:

- constipation and sluggishness of the bowel, e.g. in bedridden patients, post-operatively, in pregnancy and patients having haemorrhoids.
- diarrhoea 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 your doctor.

2. What you need to know before you take AGIOBULK®

Do not take Agiobulk®:

- If you are hypersensitive (allergic) to seeds of plantago ovata, ispaghula husk, peppermint oil or any of the other ingredients of Agiobulk® (listed in section 6).
- If you are experiencing stomach pain, nausea or vomiting.
- If you have an abnormal narrowing in the stomach and intestines and if you have difficulty in swallowing or have throat problems.
- If you experience a change in bowel habit that has lasted for more than 2 weeks.
- If you have diabetes which is not controlled.
- If you have rectal bleeding.
- If you are unable to have a bowel movement after use of a laxative.
- If you are suffering from severe water and salt losses.
- If you have abnormal faecal impaction (faecal stones).

Warnings and precautions

Take special care with AGIOBULK®:

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If you have diarrhoea and where there is no response to Agiobulk® consult your doctor so that the electrolyte levels can be checked.

Inadequate fluid intake may cause obstruction of the bowel. Agiobulk® must be taken with adequate liquid i.e. 200 ml of water (1 glass of water) for every measuring spoon of Agiobulk® (equivalent to 5 g).

If the constipation does not resolve within 3 days, if you experience abdominal pain or have irregular bowel movement, stop using Agiobulk® and seek medical advice.

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

Other medicines and AGIOBULK®:

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines).

Agiobulk® may interfere with absorption of other medicines such as minerals (e.g. calcium, iron, lithium, zinc), vitamins (vitamin B12), cardiac glycosides and coumarins.

That is why an interval of ½ to 1 hour should always be adhered to between the intake of Agiobulk® and other medicines.

Should not be used in combination with other medicines known to inhibit bowel motility (such as loperamide used to treat diarrhoea).

Thyroid hormones and Agiobulk® may only be taken together after consulting a doctor because dose adjustment of the thyroid hormones could be necessary.

If you are a diabetic, an adaptation of your anti-diabetic therapy may be required; please ask your doctor.

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Note for diabetics: A single dose of Agiobulk® (5 g) is equivalent to 0,9 g sucrose (sugar), equivalent to 0,07 bread units.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Agiobulk® may be used during pregnancy and breastfeeding. It is recommended that it be used only if constipation cannot be remedied by a change in diet.

Driving and using machines

Agiobulk® has no known effect on your ability to drive or use machines.

Contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Agiobulk®.

5 g of Agiobulk® contains approximately 0,9 g sucrose, equivalent to 0,07 bread units.

This should be taken into account in patients with diabetes mellitus.

3. How to take AGIOBULK®

Do not share medicines prescribed for you with any other person.

Always take Agiobulk® exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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The dosage as determined by your healthcare professional should not be changed.

Please adhere to the directions for use; otherwise Agiobulk® cannot act properly.

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

The usual dose:

Constipation: Take 10 g Agiobulk® (approximately two heaped medicine measures) after the evening meal (at least 1 hour before bedtime). If required, 5 g of Agiobulk® (approximately one heaped medicine measure) may also be taken in the morning before breakfast.

Diarrhoea: For the first day, and if required for another 2 days, take 10 g Agiobulk® (approximately two heaped medicines measure) 3 times daily, then if required, take 5 g of Agiobulk® (approximately one heaped medicine measure) 3 times daily.

Irritable bowel syndrome (IBS) and diverticulosis: The dosage should be determined by the doctor.

The correct dosage for each patient is the smallest amount which is necessary to produce a soft but formed stool. The laxative effect usually occurs after 8 to 12 hours.

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Unless otherwise directed, children under the age of 12 years should take half the adult dosage.

If you take more AGIOBULK® than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

In the event of overdose, the symptoms known as side effects such as bloating or sensation of fullness can be increased. Plenty of liquid should be drunk.

If you forget to take AGIOBULK®

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

Agiobulk® can have side effects.

Not all side effects reported for Agiobulk® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Agiobulk®, please consult your healthcare provider for advice.

If any of the following happens, stop taking Agiobulk® and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching
- fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to Agiobulk®. You may need urgent medical attention or hospitalisation.

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The following side effects have been reported but the frequency is unknown:

- Upon oral administration or upon skin contact Agiobulk® may cause allergic reactions such as rhinitis (nasal congestion, runny nose, sneezing, and itching), conjunctivitis (pink eye), bronchospasm (tightness of the chest) and a skin rash.
Note: In sensitised patients, peppermint oil can cause an allergic reaction (including shortness of breath).
- 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. Especially in case of insufficient fluid intake, swelling of the abdomen may occur, and there will be a risk of ileus (condition where your intestine can't push food and waste out of your body), oesophageal obstruction (leading to a sensation of choking) as well as constipation.
- Nausea and vomiting can occur.
- Water and electrolyte output may be increased due to the diarrhoea.
- In patients with ileostomy (procedure to evacuate stool from the body via the ileum instead of the usual route via the anus) there is a danger of exacerbating water and electrolyte depletion.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects 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>. By reporting side effects, you can help provide more information on the safety of Agiobulk®.

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