PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S0

Agiolax® granules

Seeds of Plantago ovata

Ispaghula husk

Tinnevelly senna pods

5 g of Agiolax® contains approximately 0,96 g sucrose.

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

Agiolax® is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use Agiolax® carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Agiolax® with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

What is in this leaflet

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

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

3. How to take Agiolax®

4. Possible side effects

5. How to store Agiolax®

6. Contents of the pack and other information

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

Agiolax® is used for the relief of constipation.

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

Do not take Agiolax®:

- If you are allergic (hypersensitive) to ispaghula husk, plantago ovata seeds, senna or any of the other ingredients listed in section 6.
- If you have an abnormal narrowing in the stomach and intestines and if you have difficulty in swallowing or have throat problems;
- If you are experiencing any stomach problems.

Warnings and precautions

Take special care with Agiolax®:

- 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 more than two weeks;
- If you are a diabetic;
- If you have rectal bleeding after using Agiolax®;
- If you are unable to have a bowel movement after using Agiolax®;
- If you are suffering from severe water and electrolyte losses;

Any intake of stimulant laxative for long periods may make bowel sluggishness worse; Agiolax® should be used only if no effective treatment can be achieved by changing the diet or by using high bulk preparations.

Other medicines and Agiolax®:

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

Inform your doctor if you take:

- Medicines for heart problems. If you use Agiolax® long-term or in very high doses, a deficiency of potassium may affect the action of medicines that are taken for heart problems.
- Medicines such as cortisone and cortisone-like substances and liquorice root. These medicines increase urine output. Potassium loss may be worsened by combining Agiolax® with these medicines.
- Intestinal absorption of other medicines, taken at the same time, may be decreased or slowed down.
- In insulin-dependent diabetics it may be necessary to reduce the insulin dose.

Pregnancy and breastfeeding and fertility

Pregnancy:

During the first three months of pregnancy, Agiolax® should be used only if constipation cannot be remedied by a change in diet or with the aid of bulking agents. Therefore, it should only be used after consultation with a healthcare professional.

Breastfeeding:

Breakdown products of senna pods have a laxative action and pass in small amounts into the maternal milk.

Driving and using machines:

It is not always possible to predict to what extent Agiolax® may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which Agiolax® affects them.

5 g of Agiolax® contains approximately 0,9 g sucrose (a type of sugar).
If you have been told by your doctor that you have intolerance to some sugars, contact your healthcare professional.
Agiolax® contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take Agiolax®

Do not share medicines prescribed for you with any other person:
Always take Agiolax® exactly as your doctor, or pharmacist. has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:
Take 5 go 10 g of **Agiolax®** (approximately one to two heaped medicines measure) after the evening meal (at least one hour before bedtime). If required, 5 g **Agiolax®** (approximately one heaped medicines measure) may also be taken in the morning before breakfast.

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

Stimulant laxatives must not be taken for long periods (more than 1 – 2 weeks) without medical advice.

If you have the impression that the effect of Agiolax® is too strong or too weak, tell your doctor or pharmacist.

If you take more Agiolax® than you should:

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

In the event of overdosage, you may experience painful intestinal cramps and severe diarrhoea with subsequent losses of water and minerals. If you have taken overdose, please consult your healthcare professional immediately. He/she will decide what countermeasures (e.g. administration of fluid and salts) may be necessary.

If you forget to take / missed a dose of Agiolax®:

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

4. Possible side effects

Agiolax® can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- Fainting
- Over-sensitivity to Plantago ovata may occur.

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

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Agiolax® should be taken with plenty of water to prevent a blockage from forming in the intestines and bowel.
- An excess amount of gas in the stomach and a feeling of fullness of bloatedness may occur.
- Mild pains as a result of colic or cramps are sometimes felt.
- The urine may become dark yellow in colour.

- Patients with inflammatory bowel disease must only use Agiolax® under the supervision of a healthcare professional.
- In cases of long-term use, diarrhoea may occur with a possible large loss of water and electrolytes, especially potassium.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "Report Drug Reaction Process", found online under SAHPRA's safety publications: https://www.sahpra.org.za/. By reporting side effects, you can help provide more information on the safety of Agiolax®.

5. How to store Agiolax®

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Store in the original container.
- Keep the container tightly closed.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label / carton / bottle.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Agiolax® contains:

The active substances in 5 g of the granules are:

Plantago ovata seeds 2,60 g

Ispaghula husks 0,11 g

Tinnevelly senna pods 0,34 – 0,66 g (corresponds to 15 mg sennoside B)

The other ingredients are:

Acacia, ferric oxides (red iron oxide, black iron oxide, yellow iron oxide), liquid and hard paraffin, aromatics (peppermint oil, caraway oil, sage oil), sucrose (approx. 0,9 g equivalent to 0,07 bread units) and talc.

What Agiolax® looks like and contents of the pack

Small-grained, medium brown granules with an aromatic odour.

Composition Container (inner lacquer PET-based) with inner lid (PP)

and screw lid (PP) of 100 g, 250 g & 1000 g and packs of 4 x 10 g sachets (paper / aluminium / PE-foil).

Holder of Certificate of Registration

VIATRIS SOUTH AFRICA (PTY) LTD

4 Brewery Street

Isando, Johannesburg,

1609

This leaflet was last revised in

3 May 2022

Registration number:

E/11.5/0988

Access to the corresponding Professional Information

Refer to the SAHPRA website: www.sahpra.co.za

Dated: 30/09/2022 Signature: 