1.3.1.1 Approved professional information

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

Agiolax® granules

2 QUALITIVE AND QUANTITIVE COMPOSITION

5 g of granules contains

Seeds of Plantago ovata	2,60 g
Ispaghula husk	0,11 g
Tinnevelly senna pods	0,34 g – 0,66 g (corresponds to 15 mg sennoside B)

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

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Small grain, medium brown granules with an aromatic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For relief of constipation.

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Dated: 03/05/2022

4.2 Posology and method of administration

Posology

Adults and children 12 years and older:

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

5 g to 10 g (half to one sachet) after the evening meal.

If necessary, the same dose should be taken before breakfast.

Note for diabetics:

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

Method of administration

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.

4.3 Contraindications

- Hypersensitivity to the ingredients.
- Intestinal obstruction, or conditions likely to lead to intestinal obstruction.
- Undiagnosed abdominal symptoms.

4.4 Special warnings and precautions for use

Agiolax® should not be used if there is abdominal pain, nausea or vomiting.

Laxatives should not be taken by patients with intestinal obstruction or with undiagnosed abdominal symptoms.

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

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Rectal bleeding or inability to have a bowel movement after the use of a laxative may indicate a serious condition. Discontinue use and consult a medical practitioner.
Inadequate fluid intake may cause obstruction of the bowel. Agiolax® should be taken with adequate liquid to prevent faecal impaction and oesophageal obstruction. Agiolax® lowers the transit time through the gut and could interfere with the absorption of other substances.
Bulk laxatives increase flatulence and distension.

Agiolax® should not be used for a period longer than one week, unless directed by a medical practitioner.
Frequent of prolonged use of laxatives, including Agiolax®, may result in loss of normal bowel function and dependence.

Prolonged use of overdosage can result in diarrhoea with excessive loss of water and electrolytes, particularly potassium. Potassium loss can produce disorders of cardiac function and myasthenia, in particular of cardiac glycosides, diuretics and adrenocortical steroids are taken concurrently. In the case of chronic use, albuminuria and haematuria can occur. There is also the possibility of developing an atonic non-functioning colon.

Anthraquinone derivatives may colour the urine yellowish-brown at acid pH, and red at alkaline pH, and may interfere with diagnostic tests.
Patients with inflammatory bowel disease must be monitored.

Each 5 g Agiolax® contains 1,04 g sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency should not take Agiolax®.

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Contains sucrose which may have an effect on the glycaemic control of patients with diabetes mellitus.

4.5 Interaction with other medicines and other forms of interaction

In cases of chronic use/abuse potassium deficiency may potentiate the action of cardiac glycosides and may affect the action of antidysrhythmic agents.

Potassium loss may be aggravated in combination with certain medicines e.g. which increase the urine output (diuretics), cortisone and cortisone-like substances (adrenocortical steroids) and liquorice root.

Intestinal absorption of medicines taken at the same time may be delayed or reduced.
In insulin-dependent diabetics it may be necessary to reduce the insulin dose.

4.6 Fertility, pregnancy and lactation

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. It should only be used after consultation with a medical practitioner.

Lactation:

Breakdown products of senna pods, such as rhein have a laxative action and pass in small amounts into the maternal milk

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4.7 Effects on ability to drive and use machines

Agiolax® does not affect the ability to drive or operate machinery.

4.8 Undesirable effects

a. Summary of the safety profile

Very rare (< 0,01 %): Hypersensitivity reactions to Plantago ovata, oesophagus obstructions, spasmodic gastro-intestinal complaints which as colic or cramps can be caused by senna, reversible pseudomelanosis coli following chronic use, which, as a rule, recedes after discontinuation of the preparation.

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 professionals are asked to report any suspected adverse reactions to SAHPRA via the "Report Drug Reaction Process", found online under SAHPRA's safety publications: https://www.sahpra.org.za/

4.9 Overdose

Treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification:

A 11.5 Laxatives

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A characteristic of **Agiolax®** is that its mode of action includes both bulk-forming properties and a stimulant effect. The bulk forming properties of Plantago ovata and Ispaghula husk increase the mass and water content of the stool, thereby accelerating colonic transit. The stimulant effect of Senna acts on the intestinal wall to increase the peristaltic movements of the colon.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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.

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

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

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

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

6.6 Special precautions for disposal of a used medicine or waste materials derived from such medicine and other handling of the product

None

7 THE HOLDER OF THE CERTIFICATE OF REGISTRATION

XIXIA PHARMACEUTICALS (PTY) LTD

4 Brewery Street

Isando

Gauteng

8 REGISTRATION NUMBER(S)

E/11.5/0988

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02 March 2012

10 DATE OF REVISION OF TEXT

3 May 2022

Sign…
Dated: 03/05/2022