Amendment date: 12 April 2019
Approval date: 26 June 2019

1.3.1.1 Package Insert (clean)

SCHEDULING STATUS

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PROPRIETARY NAME AND DOSAGE FORM

Agiolax® granules

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)

Inactive ingredients include:

Talc, acacia, ferric oxides, paraffin, aromatics, sucrose (approx. 0,9 g equivalent to 0,07 bread units).

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

PHARMACOLOGICAL CLASSIFICATION

A 11.5 Laxatives

PHARMACOLOGICAL ACTION

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.

INDICATIONS

For relief of constipation.

CONTRA-INDICATIONS

Hypersensitivity to the ingredients.

Intestinal obstruction, or conditions likely to lead to intestinal obstruction.

Undiagnosed abdominal symptoms.

WARNINGS:

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.

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 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.

INTERACTIONS:

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.

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

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.

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.

SIDE EFFECTS AND SPECIAL PRECAUTIONS

SIDE EFFECTS

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.

SPECIAL PRECAUTIONS

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.

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.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Treatment is symptomatic and supportive.

IDENTIFICATION

Small grain, medium brown granules with an aromatic odour.

PRESENTATION

Containers of 100 g, 250 g & 1000 g and packs of 4 x 10 g sachets.

STORAGE INSTRUCTIONS

Store below 25 ºC. Keep container tightly closed.

Keep out of reach of children

REGISTRATION NUMBER

E/11.5/0988

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE REGISTRATION CERTIFICATE

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DATE OF PUBLICATION OF THE PACKAGE INSERT

02 March 2012

* The granules should not be chewed or dissolved but should be swallowed whole with plenty of liquid.