

Dosage form and strength: Each 5,0 g granules contains 0,11 g ispaghula husk, 2,6 g plantago ovata seed & senna pod equivalent to 15,0 mg sennoside

Amendment date: 12 April 2019

1 **1.3.1.1 Package Insert (clean)**

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3 **SCHEDULING STATUS**

4 S0

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6 **PROPRIETARY NAME AND DOSAGE FORM**

7 **Agiolax®** granules

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9 **COMPOSITION**

10 5 g of granules contains

11 Seeds of Plantago ovata 2,60 g

12 Ispaghula husk 0,11 g

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

14

15 **Inactive ingredients include:**

16 Talc, acacia, ferric oxides, paraffin, aromatics, sucrose (approx. 0,9 g equivalent to
17 0,07 bread units).

18 **5 g granules = 7 ml = approximately 1 heaped medicine measure**

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20 **PHARMACOLOGICAL CLASSIFICATION**

21 A 11.5 Laxatives

22

23 **PHARMACOLOGICAL ACTION**

24 A characteristic of **Agiolax®** is that its mode of action includes both bulk-forming
25 properties and a stimulant effect. The bulk forming properties of Plantago ovata and

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26 Ispaghula husk increase the mass and water content of the stool, thereby
27 accelerating colonic transit. The stimulant effect of Senna acts on the intestinal wall
28 to increase the peristaltic movements of the colon.

29

30 **INDICATIONS**

31 For relief of constipation.

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33 **CONTRA-INDICATIONS**

34 Hypersensitivity to the ingredients.

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

36 Undiagnosed abdominal symptoms.

37

38 **WARNINGS:**

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

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

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

44 Rectal bleeding or inability to have a bowel movement after the use of a laxative may
45 indicate a serious condition. Discontinue use and consult a medical practitioner.

46 Inadequate fluid intake may cause obstruction of the bowel.

47 **Agiolax®** should not be used for a period longer than one week, unless directed by a
48 medical practitioner.

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49 Frequent of prolonged use of laxatives, including **Agiolax**[®], may result in los of ormal
50 bowel function and dependence.

51

52 **INTERACTIONS:**

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

55

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

59

60 Intestinal absorption of medicines taken at the same time may be delayed or reduced.

61 In insulin-dependent diabetics it may be necessary to reduce the insulin dose.

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63 **PREGNANCY AND LACTATION**

64 **PREGNANCY**

65 During the first three months of pregnancy, **Agiolax**[®] should be used only if
66 constipation cannot be remedied by a change in diet or with the aid of bulking agents.

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

68

69 **LACTATION**

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

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74 **DOSAGE AND DIRECTIONS FOR USE**

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

77

78 **Adults and children 12 years and older:**

79 **(5 g granules = 7 ml = approximately 1 heaped medicine measure.)**

80

81 5 g to 10 g (half to one sachet) after the evening meal.

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

83

84 **Note for diabetics:**

85 5 g of **Agiolax**[®] contains approximately 0,96 g sucrose.

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87 **SIDE EFFECTS AND SPECIAL PRECAUTIONS**

88 **SIDE EFFECTS**

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

93

94 **SPECIAL PRECAUTIONS**

95 **Agiolax**[®] should be taken with adequate liquid to prevent faecal impaction and
96 oesophageal obstruction. **Agiolax**[®] lowers the transit time through the gut and could

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97 interfere with the absorption of other substances. Bulk laxatives increase flatulence
98 and distension.

99

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

106

107 Anthraquinone derivatives may colour the urine yellowish-brown at acid pH, and red
108 at alkaline pH, and may interfere with diagnostic tests.

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110 Patients with inflammatory bowel disease must be monitored.

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112 **KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS** 113 **TREATMENT**

114 Treatment is symptomatic and supportive.

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116 **IDENTIFICATION**

117 Small grain, medium brown granules with an aromatic odour.

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119 **PRESENTATION**

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

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122 **STORAGE INSTRUCTIONS**

123 Store below 25 °C. Keep container tightly closed.

124 Keep out of reach of children

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126 **REGISTRATION NUMBER**

127 E/11.5/0988

128

129 **NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE REGISTRATION**

130 **CERTIFICATE**

131 XIXIA PHARMACEUTICALS (PTY) LTD

132 Building 6

133 Greenstone Hill Office Park

134 Emerald Boulevard

135 Modderfontein

136 1645

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138 **DATE OF PUBLICATION OF THE PACKAGE INSERT**

139 02 March 2012

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