PROFESSIONAL INFORMATION AGIOLAX®

AGIOLAX®

SCHEDULING STATUS S0

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 - 0,66 g (corresponds to 15 mg sennoside B)

Inactive ingredients include: Talc, acacia, ferric oxides, paraffin, aromatics
Contains sugar: sucrose (approx. 1,05 g equivalent to 0,09 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.

CONTRAINDICATIONS
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 or prolonged use of laxatives, including **Agiolax®**, may result in loss of normal bowel function and dependence.
Contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucraseisomaltase insufficiency should not take **Agiolax®**. Contains sucrose which may have an effect on the glycaemic control of patients with diabetes mellitus.

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 1,05 g sucrose.

SIDE EFFECTS AND SPECIAL PRECAUTIONS
Side effects
Very rare (< 0,01 %): Hypersensitivity reactions to Plantago ovata, oesophageal obstructions, spasmodic gastrointestinal complaints such as colic or cramps can be caused by senna, and 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 or 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 when 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-grained, medium brown granules with an aromatic odour.

PRESENTATION
Containers of 100 g, 250 g, 400 g and 1000 g and packs of 4 x 10 g or 30 x 10 g sachets.

STORAGE INSTRUCTIONS
Store at or below 25 °C. 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 CERTIFICATE OF REGISTRATION
XIXIA PHARMACEUTICALS (PTY) LTD
4 Brewery Street, Isando, Kempton Park, 1600
Republic of South Africa

DATE OF PUBLICATION OF THE PACKAGE INSERT
02 March 2012

Namibia Reg. No.: 90/11.5/00508

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

Mylan

www.mylansa.co.za

PROFESSIONELE INFORMASIE

AGIOLAX®

SKEDULERINGSTATUS S0

EIENDOMSNAAM EN DOSEERVORM
AGIOLAX® (korrels)

SAMESTELLING
5 g korrels bevat:

Sade van Plantago ovata	2,60 g
Ispaghula doppe	0,11 g
Tinnevelly senna-peule	0,34 g - 0,66 g (gelykstaande aan 15 mg sennosied-B)

Onaktiewe bestanddele sluit in:
Talk, akasia, ysteroksides, paraffien, aromatiese middels
Bevat suiker: sukrose (ongeveer 1,05 g ekwivalent aan 0,09 broodeenhede).
5 g korrels = 7 ml = ongeveer 1 opgehoopte medisynemaat

FARMAKOLOGIESE KLASSIFIKASIE
A. 11.5 Lakseermiddels

FARMAKOLOGIESE WERKING
'n Kenmerk van **Agiolax®** is dat sy werkingsmetode beide massavormende eienskappe en 'n stimulerende effek insluit. Die massavormende eienskappe van Plantago ovata en Ispaghula doppe vermeerder die massa- en waterinhoud van die stoelgang, waardeur beweging deur die kolon versnel word. Die stimulerende effek van Senna werk op die dermwand om die peristaltiese bewegings van die kolon te vermeerder.

INDIKASIES
Vir die verligting van hardlywigheid.

KONTRA-INDIKASIES
Hipersensitiwiteit teenoor die bestanddele. Intestinale obstruksie, of toestande wat geneig is om tot intestinale obstruksies te lei. Ongediagnoseerde abdominale simptome.

WAARSKUWINGS
Agiolax® behoort nie gebruik te word indien daar abdominale pyn, naarheid en braking teenwoordig is nie. Lakseermiddels behoort nie deur pasiënte met intestinale obstruksie of met ongediagnoseerde abdominale simptome geneem te word nie.
Indien 'n verandering in ontlasting voorkom en vir langer as twee weke aanhou, behoort 'n mediese praktisyn geraadpleeg te word om die oorsaak vas te stel.
Rektale bloeding of onvermoë om te ontlas na die gebruik van 'n lakseermiddel, mag 'n ernstige toestand aandui. Staak gebruik en raadpleeg 'n mediese praktisyn.
Onvoldoende vloeistofinname mag obstruksie van die derm veroorsaak.
Bevat sukrose. Pasiënte met seldsame oorerflike probleme soos fruktose intoleransie, glukose-galaktose wanabsorpsie of sukrase-isomaltase ontoereikendheid, moet nie **Agiolax®** neem nie.
Bevat sukrose, wat 'n effek mag hê op die glisemiese beheer van pasiënte met diabetes mellitus.

INTERAKSIES
In gevalle van chroniese gebruik/misbruik mag kaliumgebrek die werking van kardiale glikosiede potensieer en die werking van antidisritmiese middels affekteer.
Verlies van kalium mag in kombinasie met sekere medisyne, bv. diuretika, kortisoon en kortisoon-agtige stowwe (adrenokortikale steroïede) en soetwortel, vererger word.
Intestinale absorpsie van medisyne wat gelyktydig geneem word, mag vertraag of verminder word. By insulien-afhanklike diabete mag dit nodig wees om die insulien dosis te verminder.

SWANGERSKAP EN LAKTASIE
Swangerskap
Tydens die eerste drie maande van swangerskap, behoort **Agiolax®** slegs gebruik te word indien hardlywigheid nie deur 'n verandering in dieet of met behulp van massavormende middels herstel kan word nie. Dit behoort slegs na konsultasie met 'n mediese praktisyn, gebruik te word.

Laktasie
Afbraakprodukte van senna-peule, soos rhein het 'n lakseringswerking en klein hoeveelhedeword na die moeder se melk oorgedra.

DOSIS EN GEBRUIKSAANWYSINGS
Die korrels behoort met 'n vol glas vloeistof (verkieslik water) ingesluk te word. Die korrels behoort heel ingesluk te word en nie gekou of opgelos nie.
Volwassenes en kinders van 12 jaar en ouer:
(5 g korrels = 7 ml = ongeveer 1 opgehoopte medisynemaat.)
5 g tot 10 g ('n halwe tot een sakkie) na aandete. Indien nodig kan dieselfde dosis voor ontbyt geneem word.
Nota aan diabete: 5 g **Agiolax®** bevat ongeveer 1,05 g sukrose.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:
Newe-effekte
Baie seldsaam (< 0,01 %): Hipersensitiwiteitsreaksies teenoor Plantago ovata, esofageale obstruksies, spasmodiese gastroïntestinale klagtes soos koliek of krampe kan deur senna veroorsaak word, en omkeerbare pseudomelanosis coli na chroniese gebruik, wat gewoonlik na staking van die preparaat afneem.

Spesiale Voorsorgmaatreëls
Agiolax® behoort met genoegsame vloeistof geneem te word om fekale impaksie en esofageale obstruksie te voorkom. **Agiolax®** verminder die deurgang deur die derm en kan moontlik inmeng met die absorpsie van ander stowwe. Massavormende lakseermiddels vermeerder winde en uitsetting.
Verlengde gebruik of oordosering kan diarree veroorsaak met oormatige verlies van water en elektroliete, veral kalium. Verlies van kalium kan versteurings van hartfunksie en miastenie veroorsaak, veral indien kardiale glikosiede, diuretika en adrenokortikale steroïede gelyktydig geneem word. In die geval van chroniese gebruik, kan albuminurie en hematurie voorkom. Daar bestaan ook 'n moontlikheid dat 'n atoniese nie-funksionerende kolon mag ontwikkel.
Antrakinoon-derivate mag die urine by 'n suur pH geel-bruin verkleur, en by 'n alkaliese pH rooi verkleur, en mag met diagnostiese toetse inmeng.
Pasiënte met inflammatoriese dermsiekte moet gemoniteer word.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN
Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE
Klein gekorrelde, medium bruin korrels met 'n aromatiese geur.

AANBIEDING
Houers van 100 g, 250 g, 400 g & 1000 g en pakke van 4 x 10 g of 30 x 10 g sakkies.

BEWARINGSINSTRUKSIES
Bewaar teen of benede 25 °C. Die houer moet dig gesluit gehou word.
HOU BUITE BEREIK VAN KINDERS

REGISTRASIENOMMER
E/11.5/0988

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:
XIXIA PHARMACEUTICALS (PTY) LTD
4 Brewery Street, Isando, Kempton Park, 1600
Republiek van Suid-Afrika

Mylan

www.mylansa.co.za

DATUM VAN PUBLIKASIE VAN DIE VOUBILJET
02 Maart 2012

Namibië Reg. Nr.: 90/11.5/00508

Die korrels behoort nie gekou of opgelos te word nie, maar moet heel, met baie vloeistof, ingesluk word.

56ZA2149261-00 / 902782