SCHEDULING STATUS: S0

PROPRIETARY NAME (and dosage form):

Dulcolax® 10 mg
SUPPOSITORIES

Dulcolax® 5 mg
SUPPOSITORIES

COMPOSITION:
Each adult suppository contains bisacodyl 10 mg.
Each paediatric suppository contains bisacodyl 5 mg.

PHARMACOLOGICAL CLASSIFICATION:
A 11.5 Laxatives

PHARMACOLOGICAL ACTION:
DULCOLAX is a laxative that acts by one or more actions on the colonic mucosa to produce effective peristalsis and evacuation of the bowel.

INDICATIONS:
For the relief of occasional constipation.

CONTRA-INDICATIONS:
Known hypersensitivity to bisacodyl.
Ileus, intestinal obstruction, undiagnosed abdominal symptoms or acute surgical abdominal conditions like acute appendicitis, acute inflammatory bowel disease and in severe dehydration.

WARNINGS:
This medicine should not be used in the presence of abdominal pain, nausea or vomiting. Frequent or prolonged use of this preparation may result in dependence on laxatives and loss of normal bowel function.
If you have noticed a sudden change in bowel habits that has persisted for a period of greater than 2 weeks, consult a doctor before using the laxative.
This product should not be used for a period longer than one week, unless directed by a doctor.
If a laxative is needed every day, the cause of constipation should be investigated.
Rectal bleeding or failure to have a bowel movement after use of a laxative, may indicate a serious condition. Discontinue use and consult a doctor.

INTERACTIONS:
The concomitant use of diuretics or adreno-corticosteroids may increase the risk of electrolyte imbalance if excessive doses of DULCOLAX are taken. Electrolyte imbalance may lead to increased sensitivity to cardiac glycosides.

PREGNANCY AND LACTATION:
Safety in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:
Unless otherwise prescribed by your doctor, the following dosages are recommended:

Suppositories:
The suppositories should be unwrapped and inserted into the rectum pointed end first. Bowel movement is generally produced within 15 minutes to one hour.

Adults and children 12 years and over:
One 10 mg suppository as a single daily dose.
Children 1–12 years:
One 5 mg suppository as a single daily dose.

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SIDE-EFFECTS AND SPECIAL PRECAUTIONS:
Side-effects:
DULCOLAX may cause abdominal discomfort, diarrhoea, abdominal pain and abdominal cramps.
Allergic reactions, including isolated cases of angio-oedema and anaphylactoid reactions have been reported in association with the administration of DULCOLAX.

Special precautions:
Prolonged use may lead to diarrhoea with excessive loss of water and electrolytes, particularly potassium, and possible atonic non-functioning colon.
Dizziness and/or syncope have been reported in patients who have taken DULCOLAX.
Administration of suppositories may cause local irritation.
Repeated use may cause proctitis or sloughing of the epithelium.
The suppositories should be used with caution in patients with rectal fissures or ulcerated haemorrhoids.
Care should be taken in patients with inflammatory bowel disease.
Children should not take DULCOLAX without medical advice.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Symptoms:
If high doses are taken watery stools (diarrhoea), abdominal cramps and a clinically significant loss of potassium and other electrolytes can occur. Chronic overdose with DULCOLAX may cause chronic diarrhoea, abdominal pain, hypokalaemia, secondary hyperaldosteronism and renal calculi. Renal tubular damage, metabolic alkalosis and muscle weakness secondary to hypokalaemia have also been described in association with chronic laxative abuse.

Therapy:
Replacement of fluids and correction of electrolyte imbalance may be required. This is especially important in the elderly and the young.

IDENTIFICATION:
DULCOLAX 5 mg suppositories and DULCOLAX 10 mg suppositories – smooth, white or slightly yellow, torpedo-shaped suppositories in aluminium foil with the name printed on the foil.

PRESENTATION:
DULCOLAX 10 mg suppositories – Boxes of 10 suppositories.
DULCOLAX 5 mg suppositories – Boxes of 10 suppositories.

STORAGE INSTRUCTIONS:
Do not store above 25 °C. Keep out of reach of children.

REGISTRATION NUMBERS:
DULCOLAX 10 mg suppositories: E/11.5/532
DULCOLAX 5 mg suppositories: E/11.5/534

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
sanofi-aventis south africa (pty) ltd
2 Bond Street,
1685, Midrand, SA

DATE OF PUBLICATION OF THIS PACKAGE INSERT:
20 September 2013

BOTSWANA Reg. No.		S3
DULCOLAX 5 mg Suppositories	B9305045	
DULCOLAX 10 mg Suppositories	B9305040	

NAMIBIA Reg. No.		NS0
DULCOLAX 5 mg Suppositories	04/11.5/0976	
DULCOLAX 10 mg Suppositories	04/11.5/0974	

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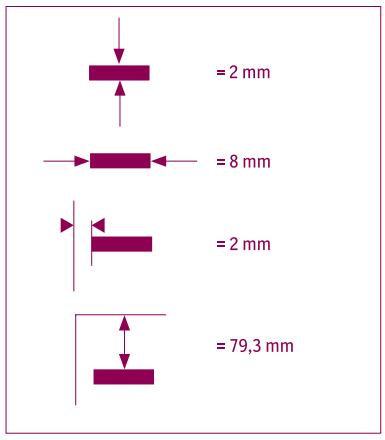
PITCH CODE



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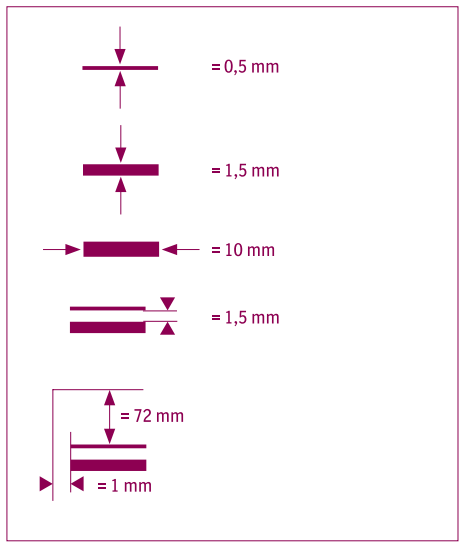

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File information

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Market:	ZA
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Issue date of artwork:	15/Aug/2017
Print colors:	Pan 357
Number of print colors:	1
Used font:	Bliss 2
Min. font size:	6 pt
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Technical colors

Diecut-Legendcase		Free area		Glue points	

Additional Requirements of Packaging Site

Dimensions: mm 160x215,9

SKEDULERINGSTATUS: S0

EIENDOMSNAAM (en doseervorm):

Dulcolax® 10 mg
SETPILLE

Dulcolax® 5 mg
SETPILLE

SAMESTELLING:
Elke volwassene setpil bevat 10 mg bisakodiel.
Elke pediatriese setpil bevat 5 mg bisakodiel.

FARMAKOLOGIESE KLASSIFIKASIE:
A 11.5 Lakseermiddels

FARMAKOLOGIESE WERKING:
DULCOLAX is 'n lakseermiddel wat sy werking uitvoer deur een of meer aksies op die slymvlies van die kolon om doeltreffende peristalse en lediging van die derm te bewerkstellig.

INDIKASIES:
Vir die verligting van toevallige hardlywigheid.

KONTRA-INDIKASIES:
Bekende hipersensitiwiteit vir bisakodiel.
Ileus, intestinale obstruksie, ongediagnoseerde abdominale simptome of akute chirurgiese abdominale toestande soos akute blindedermontsteking, akute inflammatoriese ingewandsiekte en in ernstige dehidrasie.

WAARSKUWINGS:
Hierdie medisyne moet nie gebruik word wanneer buikpyn, naarheid of braking voorkom nie. Gereelde of verlengde gebruik van hierdie preparaat mag tot afhanklikheid van lakseermiddels en 'n verlies van normale dermfunksie lei.
Indien u 'n skielike verandering in u dermbewegings waarneem wat vir langer as 2 weke voortduur, moet u 'n dokter raadpleeg voordat u hierdie lakseermiddel gebruik.
Tensy deur 'n dokter voorgeskryf, moet hierdie produk nie vir 'n periode van langer as een week gebruik word nie.
Indien u 'n lakseermiddel daagliks benodig, moet die oorsaak van hardlywigheid ondersoek word.
Rektale bloeding of 'n weiering van dermbewegings na die gebruik van 'n lakseermiddel mag op 'n ernstige kondisie dui. Staak die gebruik en raadpleeg 'n dokter.

INTERAKSIES:
Die gelyktydige gebruik van diuretika of adreno-kortikosteroïede mag die risiko van elektroliet wanbalans verhoog indien uitermatige dosisse van DULCOLAX geneem word.
Elektroliet wanbalans kan lei tot verhoogde sensitiwiteit vir kardiale glikosiede.

SWANGERSKAP EN LAKTASIE:
Veiligheid in swangerskap en laktasie is nog nie vasgestel nie.

DOSIS EN GEBRUIKSAANWYSINGS:
Die volgende dosisse word aanbeveel, tensy anders voorgeskryf deur u geneesheer:

Setpille:
Die setpille moet verwyder word uit die foelie en in die rektum geplaas word met die gepunte kant eerste. Dermbewegings word gewoonlik binne 15 minute tot een uur teweeggebring.

Volwassenes en kinders ouer as 12 jaar:
Een 10 mg setpil as 'n enkele daaglikse dosis.
Kinders van 1–12 jaar:
Een 5 mg setpil as 'n enkele daaglikse dosis.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:
Newe-effekte:
DULCOLAX mag buikongemak, diaree, buikpyn en -krampe veroorsaak.
Allergiese reaksies, insluitend geïsoleerde gevalle van angioëdeem en anafilaktoïede reaksies, is aangemeld tydens die gebruik van DULCOLAX.

Spesiale voorsorgmaatreëls:
Verlengde gebruik mag lei tot diaree met 'n oormatige verlies aan water en elektroliete, veral kalium en 'n moontlike atoniese, nie-funksionerende kolon.
Duiseligheid en/of floutes is aangemeld in pasiënte wat DULCOLAX gebruik het.
Die toediening van setpille mag 'n lokale irritasie veroorsaak.
Herhaalde gebruik mag proktitis of roofvorming van die epiteel veroorsaak.
Die setpille moet met sorg gebruik word in pasiënte met rektale fissure of bloeiende aambeie.
Sorg moet geneem word in pasiënte met inflammatoriese dermsiekte.
Kinders moet nie DULCOLAX neem sonder mediese advies nie.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Simptome:
Indien hoë dosisse geneem word, kan waterige stoelgang (diaree), buikkrampe en 'n klinies betekenisvolle verlies van kalium en ander elektroliete voorkom.
Chroniese oordosering met DULCOLAX mag chroniese diaree, buikpyn, hipokalemie, sekondêre hiperaldosteronisme en nierstene veroorsaak.
Beskadiging van die nierbuise, metaboliese alkalose en spierswakheid sekondêr tot hipokalemie, is ook beskryf tydens die chroniese misbruik van lakseermiddels.

Terapie:
Vervanging van vloeistowwe en die herstel van die elektroliet wanbalans mag nodig wees. Dis veral belangrik by bejaardes en kinders.

INDENTIFIKASIE:
DULCOLAX 5 mg setpille en DULCOLAX 10 mg setpille - gladde, wit of effens geel, torpedovormige setpille in aluminiumfoelie, met die naam op die foelie gedruk.

AANBIEDING:
DULCOLAX 10 mg setpille – Dosies met 10 setpille.
DULCOLAX 5 mg setpille – Dosies met 10 setpille.

BERGINGSINSTRUKSIES:
Moenie bo 25 °C geberg word nie. Hou buite bereik van kinders.

REGISTRASIENOMMERS:
DULCOLAX 10 mg setpille: E/11.5/532
DULCOLAX 5 mg setpille: E/11.5/534

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:
sanofi-aventis south africa (edms) bpk
Bondstraat 2,
1685, Midrand, SA

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:
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