SCHEDULING STATUS: S0

PROPRIETARY NAME (and dosage form):

Dulcolax® tablets

COMPOSITION:
Each coated tablet contains bisacodyl 5 mg.
Contains sugar.

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:

Tablets:
Bowel movement is generally produced within 6 to 12 hours.
Adults and children 12 years and over: 1–3 tablets as a single daily dose.
Children 6 years to under 12 years: 1 tablet as a single daily dose.

The tablets should be swallowed whole with adequate fluid.

The tablets should be taken at night to produce evacuation the following morning.

Do not give to children under 6 years of age or to persons who cannot swallow without chewing, unless directed by a doctor.

Do not take this product within one hour after taking an antacid or milk.

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. The details available for these cases suggest that the events would be consistent with defecation syncope (or syncope attributable to straining at stool), or with a vasovagal response to abdominal pain, which may be related to the constipation that prompted the patients in question to resort to the use of laxatives and not necessarily to the administration of DULCOLAX itself.
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:
Within a short period of time after ingestion of oral dosage forms of DULCOLAX, absorption can be minimised or prevented by inducing vomiting or gastric lavage. Replacement of fluids and correction of electrolyte imbalance may be required. This is especially important in the elderly and the young.

IDENTIFICATION:
Round, beige-yellow, biconvex sugar/enteric coated tablets with a smooth, shiny surface and a white core.

PRESENTATION:
Opaque white PVC/PVDC/silver aluminium foil blister packs of 10, 30, 40, 60 and 200 tablets.

STORAGE INSTRUCTIONS:
Store at or below 30 °C. Keep out of reach of children.

REGISTRATION NUMBER:
E/11.5/531

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.: B9305035	S3
NAMIBIA Reg. No.: 04/11.5/0975	NS0

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pack2edit
Digital · Packaging · Development

SANOFI

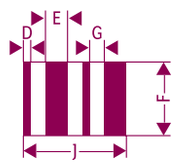
File information

GMID code:	651797 / 651812 / 651834 / 651839 / 651843
Plant PM code:	1060017581
Second Plant PM code:	318614-06
Version of artwork:	V1
PM type:	PI
Market:	ZA
Format:	160 x 210 mm
Issue date of artwork:	27/Jun/2017
Print colors:	Pan 357
Number of print colors:	1
Used font:	Bliss 2
Min. font size:	6 pt
p2e number:	903399

Technical colors

Diecut-Legendcase		Free area		Glue points	

ADDITIONAL REQUIREMENT OF PACKAGING LINE			
Description :	PI DULCOLAX 5MG DG ZA		
Dimension :	160 x 210 mm		
No. of code :	566		
Ref. drawing :	PR30	**Issue date of TD:**	23/06/2017



MASS D 0,5 mm
MASS E 1,5 mm
MASS G 1,0 mm
MASS F 6,0 mm

Example
Technical information control code

SKEDULERINGSTATUS: S0

EIENDOMSNAAM (en doseervorm):

Dulcolax®
tablette

SAMESTELLING:
Elke bedekte tablet bevat 5 mg bisakodiel.
Bevat suiker.

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 blindedermonsteking, akute inflammatoriese ingewandsiekte en in ernstige dehidrasie.

WAARSKUWINGS:
Hierdie medisyne moet nie gebruik word wanneer abdominale pyn, naarheid of braking voorkom nie. Gereelde of verlengde gebruik van hierdie medikasie mag tot afhanklikheid van lakseermiddels en 'n verlies van normale dermfunksie lei.

Indien jy 'n skielike verandering in jou dermbewegings waarneem wat vir langer as 2 weke voortduur, moet jy 'n dokter raadpleeg voordat jy hierdie lakseermiddel gebruik.

Tensy deur 'n dokter voorgeskryf, moet hierdie produk nie vir 'n periode van langer as een week gebruik word nie.

Indien jy 'n lakseermiddel daagliks benodig, moet die oorsaak van die hardlywigheid ondersoek word.

Rektale bloeding of 'n staking van dermbewegings na die gebruik van 'n lakseermiddel mag op 'n ernstige toestand 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 jou geneesheer:

Tablette:
Dermbewegings word gewoonlik binne 6–12 ure teweeggebring.
Volwassenes en kinders ouer as 12 jaar: 1–3 tablette as 'n enkel daaglikse dosis.
Kinders van 6–12 jaar: 1 tablet as 'n enkel daaglikse dosis.

Die tablette moet heel gesluk word met voldoende vloeistof.

Die tablette moet saans geneem word sodat ontlasting die volgende oggend kan volg.

Moenie aan persone jonger as 6 jaar, of aan persone wat nie kan sluk sonder om te kou gegee word nie, tensy dit deur 'n dokter aanbeveel word.

Moenie hierdie middel gebruik binne een uur nadat 'n teensuurmiddel of melk ingeneem is nie.

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-funksionele kolon.
Duiseligheid en/of floutes is aangemeld in pasiënte wat DULCOLAX gebruik het. Besonderhede van hierdie gevalle dui daarop dat dit ooreenstem met ontlasting floutes (of floutes toegeskryf aan hardlywigheid), of met 'n vasovagale reaksie tot buikpyn, as gevolg van hardlywigheid wat aanleiding daartoe gegee het dat die pasiënt hom/haar gewend het tot die gebruik van 'n lakseermiddel en nie noodwendig tot die toediening van DULCOLAX self nie.
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), abdominale krampe 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:
Absorpsie kan verminder of voorkom word indien daar binne 'n kort tydsverloop na die inname van die orale doseervorme van DULCOLAX, braking of maagspoeling geïnduseer word.
Vervanging van vloeistowwe en die herstel van die elektroliet wanbalans mag nodig wees. Dis veral belangrik by bejaardes en kinders.

IDENTIFIKASIE:
Ronde, beige-geel, bikonvekse suiker/enteries bedekte tablette met 'n gladde, blink oppervlak en 'n wit kern.

AANBIEDING:
Ondeursigtige, wit PVC/PVDC/silwer aluminium foelie stolpverpakkings van pakke van 10, 30, 40, 60 en 200 tablette.

BERGINGSINSTRUKSIES:
Bewaar teen of benede 30 °C. Hou buite bereik van kinders.

REGISTRASIENOMMER:
E/11.5/531

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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