## STOOL SOFTENER PLUS STIMULANT LAXATIVE- docusate sodium and sennosides tablet Dolgencorp, Inc. (DOLLAR GENERAL & REXALL)

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

-----

#### **Drug Facts**

#### **Active ingredients (in each tablet)**

Docusate sodium 50 mg

Sennosides 8.6 mg

#### Purpose

Stool softener

Stimulant laxative

#### Uses

- for overnight relief from occasional constipation (irregularity)
- generally produces bowel movement in 6 to 12 hours

#### Warnings

#### Do not use

- laxative products for longer than 1 week unless told to do so by a doctor
- if you are presently taking mineral oil, unless told to do so by a doctor

#### Ask a doctor before use if you have

- stomach pain
- nausea
- vomiting
- noticed a sudden change in bowel habits that lasts over a period of 2 weeks

#### Stop use and ask a doctor if

you have rectal bleeding or fail to have a bowel movement after use of a laxative. These could be signs of a serious condition.

#### If pregnant or breast-feeding,

ask a health professional before use.

#### Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

#### **Directions**

• Take only by mouth. Doses may be taken as a single daily dose, preferably in the evening, or in divided doses.

adults and children 12 years and older	take 2-4 tablets daily
children 6 to under 12 years of age	take 1-2 tablets daily
children 2 to under 6 years of age	take up to 1 tablet daily
children under 2	ask a doctor

#### Other information

- each tablet contains: calcium 20 mg
- each tablet contains: sodium 6 mg VERY LOW SODIUM
- store at 25°C (77°F), protect from heat, light, and moisture

#### **Inactive ingredients**

carnauba wax\*, croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C blue #2 aluminum lake, FD&C red #40 aluminum lake, hypromellose, magnesium stearate, maltodextrin\*, microcrystalline cellulose, polyethylene glycol\*, polyvinyl alcohol\*, silcon dioxide, sodium benzoate\*, stearic acid, talc\*, titanium dioxide

#### Questions or comments?

Call 1-888-309-9030

#### **Principal Display Panel**

Compare to the active ingredients of Peri-Colace®\*\*

#### **Stool Softener Plus Stimulant Laxative**

Docusate Sodium 50 mg

Sennosides 8.6 mg

For Overnight Relief of Occasional Constipation

- Effective
- Reliable
- Comfortable

#### **TABLETS**

\*\*This product is not manufactured or distributed by Purdue Products L.P., distributor of Peri-Colace®.

## TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

DISTRIBUTED BY DOLGENCORP, LLC 100 MISSION RIDGE

GOODLETTSVILLE, TN 37072

#### **Product Label**

<sup>\*</sup>contains one or more of these ingredients



## contains one or more of these ingredients I store at 25°C (77°F), protect from heat, light, and

dihydrate, FD&C blue #2 aluminum lake, FD&C red #40 glycol, polyvinyl alcohol\*, silicon dioxide, sodium benzoate\* stearic acid, talc\*, titanium dioxide maltodextrin\*, microcrystalline cellulose, polyethylene aluminum lake, hypromellose\*, magnesium stearate, croscarmellose sodium, dibasic calcium phosphate nactive ingredients camauba wax\* Other information Directions

take only by mouth. Doses may be taken as a single children under 2 12 years of age children 2 to under 6 12 years and older years of age children 6 to under adults and children daily dose, preferably in the evening, or in divided doses take 2-4 tablets daily take 1-2 tablets daily ask a doctor take up to 1 tablet daily

# Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional Stop use and ask a doctor if you have rectal bleeding or fail to have a bowel movement after use of a laxative. hese may indicate a serious condition.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

**DOLLAR GENERAL Stool Softener plus Stimulant Laxative** 

each tablet contains: calcium 20 mg

each tablet contains: sodium 6 mg VERY LOW SODIUN

#### STOOL SOFTENER PLUS STIMULANT LAXATIVE

Questions or comments:

docusate sodium and sennosides tablet

#### **Product Information** Product Type HUMAN OTC DRUG Item Code (Source) NDC:55910-084 **Route of Administration** ORAL

Active Ingredient/Active Moiety			
ı	Ingredient Name	Basis of Strength	Strength
ı	DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg
ı	SENNO SIDES (UNII: 3FYP5M0 IJX) (SENNO SIDES - UNII: 3FYP5M0 IJX)	SENNOSIDES	8.6 mg

Inactive Ingredients		
Ingredient Name	Strength	
CARNAUBA WAX (UNII: R12CBM0EIZ)		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
DIBASIC CALCIUM PHO SPHATE DIHYDRATE (UNII: O7TSZ97GEP)		

FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYPROMELLOSES (UNII: 3NXW29 V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SILICON DIO XIDE (UNII: ETJ7Z6XBU4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
ALUMINUM O XIDE (UNII: LMI26O6933)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

Product Characteristics			
Color	RED	Score	no score
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	TCL097;0806;AV;S44
Contains			

ı	Packaging				
	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
	1 NDC:55910-084-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2018	12/30/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	04/30/2018	12/30/2021

### Labeler - Dolgencorp, Inc. (DOLLAR GENERAL & REXALL) (068331990)

Revised: 12/2019 Dolgencorp, Inc. (DOLLAR GENERAL & REXALL)