

DOCUSATE SODIUM WITH SENNOSIDES- docusate sodium 50mg and sennosides 8.6mg tablet, film coated
PD-Rx Pharmaceuticals, Inc.

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)

Sennosides from Senna Concentrate 8.6mg

Docusate Sodium 50mg

Purpose

Laxative

Stool Softner

Uses

- relieves occasional constipation (irregularity)
- generally produces a bowel movement in 6-12 hours

Warnings

Do not use

- laxative products for longer than 1 week unless directed by a doctor
- if you are taking mineral oil, unless directed by a doctor

Ask a doctor before use if you have

- stomach pain
- nausea
- vomiting
- noticed a sudden change in bowel habits that continues 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 the use of a laxative. These may indicate a serious condition.

If pregnant or breast feeding,

ask a healthcare professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.(800) 222-1222.

Directions

- take preferably at bedtime or as directed by a doctor

age	starting dosage	maximum dosage
Adults and children 12 years and over	2 tablets once daily	4 tablets twice daily
Children 6 to under 12 years	1 tablet once daily	2 tablets twice daily
Children 2 to under 6 years	1/2 tablet once daily	1 tablet twice daily
Children under 2 years	ask a doctor	ask a doctor

Other information

- each tablet contains **10 mg of calcium, sodium 5 mg**
- store at 25°(77°F); excursions permitted between 15 °-30 °C (59 °-86 °F)

Inactive ingredients

crosscarmellose Sodium, D&C Yellow# 10, dicalcium phosphate, FD&C Yellow #6, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol, polyethylene glycol, sodium benzoate, talc, titanium dioxide

Questions or comments?

(866) 562-2756 Mon-Fri 8 AM to 4 PM EST

16 HOW SUPPLIED/STORAGE AND HANDLING

Docusate Sodium with Sennosides is a orange, round tablet; Debossed with PH32.

Bottles of 100 NDC 43063-958-01

Bottles of 1000 NDC 43063-958-95

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F).

NDC 43063-958-01

Manufactured in the USA

***Compare to the active ingredients in Senokot-S®**

**Docusate Sodium 50mg &
Sennosides 8.6mg
Natural Vegetable Laxative
Ingredient Plus Stool Softner
100 TABLETS**

Drug Facts	
Active Ingredients (in each tablet)	Purposes
Docusate Sodium 50 mg _____ Stool softener Sennosides from Senna Concentrate 8.6 mg _____ Laxative	
Uses:	
<ul style="list-style-type: none"> relieves occasional constipation (irregularity) generally produces a bowel movement in 6-12 hours. 	
Warnings:	
Do not use • laxative products for longer than 1 week unless directed by a doctor • if you are taking mineral oil, unless directed by a doctor	
Ask a doctor before use if you have	
<ul style="list-style-type: none"> stomach pain • nausea • vomiting • noticed a sudden change in bowel habits that continues over a period of 2 weeks 	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> you have rectal bleeding or you fail to have a bowel movement after the use of a laxative. These may indicate a serious condition. 	
If pregnant or breast-feeding, ask a healthcare professional before use.	

NDC 43063-958-01 Stool Softner Plus Natural Vegetable Laxative



Docusate Sodium 50 mg
With Sennosides 8.6 mg



GTIN: 00343063958018
SNO: H19A280002
EXP: 210831
LOT: H19A28

Marketed and Packaged By:
PD-Rx Pharmaceuticals, Inc
Oklahoma City, OK 73127
1-405-942-3040

100 Tablets
TAMPER EVIDENT: DO NOT USE IF
SEAL IS BROKEN OR MISSING FROM BOTTLE.

Drug Facts (continued)		
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (800) 222-1222 v.8.19.0		
Directions:		
• take preferably at bedtime or as directed by a doctor		
age	starting dosage	maximum dosage
adults and children 12 years and over	2 tablets once a day	4 tablets twice a day
children 6 to 12 years	1 tablet once a day	2 tablets twice a day
children 2 to under 6 years	1/2 tablet once a day	1 tablet twice a day
children under 2 years	Ask a doctor	Ask a doctor
Other information		
• each tablet contains: 10 mg of calcium, 5 mg of sodium • store at 25° C (77°F); excursions permitted between 15°- 30°C (59° - 86°F)		
Inactive ingredients: croscarmellose sodium, D&C Yellow #10, dicalcium phosphate, FD&C Yellow #6, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide		
Questions or comments? (866) 562-2756 Mon-Fri 8 AM to 4 PM EST		

Lot:H19A28Exp:08/2021

DOCUSATE SODIUM WITH SENNOSIDES

docusate sodium 50mg and sennosides 8.6mg tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43063-958(NDC:16103-378)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SENNOSIDES (UNII: 3FYP5M0J1X) (SENNOSIDES - UNII:3FYP5M0J1X)	SENNOSIDES	8.6 mg
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange (ORANGE COLOR)	Score	no score
Shape	ROUND (ROUND TABLET)	Size	10mm
Flavor		Imprint Code	PH32
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43063-958-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/21/2019	
2	NDC:43063-958-95	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/17/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	11/05/2018	

Labeler - PD-Rx Pharmaceuticals, Inc. (156893695)

Registrant - PD-Rx Pharmaceuticals, Inc. (156893695)

Establishment

Name	Address	ID/FEI	Business Operations
PD-Rx Pharmaceuticals, Inc.		156893695	repack(43063-958)

Revised: 12/2021

PD-Rx Pharmaceuticals, Inc.