STOOL SOFTENER- docusate sodium capsule, liquid filled Preferred Plus (Kinray)

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 ingredient (in each softgel)

Docusate sodium 100 mg

Purpose

Stool softener laxative

Uses

- relieves occasional constipation (irregularity)
- generally produces bowel movement in 12 to 72 hours

Warnings

Do not use

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 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.
- you need to use a laxative for more than 1 week

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 or in divided doses.

adults and children 12 years and over	take 1-3 softgels daily
children 2 to under 12 years of age	take 1 softgel daily
children under 2 years	ask a doctor

Other information

- each softgel contains: sodium 6 mg
- store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F)

Inactive ingredients

D&C red #33*, D&C yellow #10*, edible ink, FD&C blue #1*, FD&C red #40, FD&C yellow #6, gelatin, glycerin, lecithin*, medium-chain triglycerides*, polyethylene glycol, propylene glycol*, purified water, sorbitan, sorbitol, titanium dioxide

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

Stool Softener

†Compare To the Active Ingredient in Colace®

Each softgel contains 100 mg Docusate Sodium

SOFTGELS

Distributed by: Kinray, Inc.

152-35 Tenth Avenue

Whitestone, NY 11357

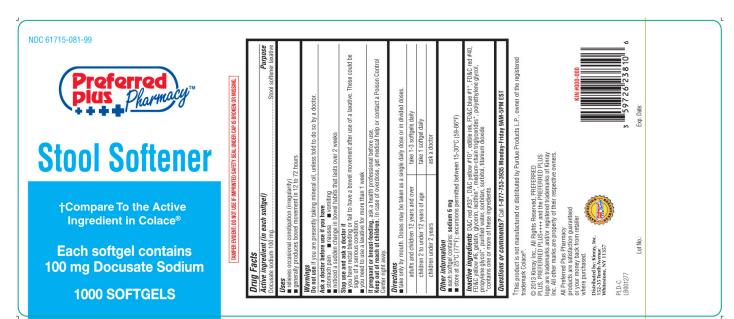
†This product is not manufactured or distributed by Purdue Products L.P., owner of the registered trademark Colace®.

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

©2013 Kinray Inc., All Rights Reserved, PREFERRED PLUS, PREFERRED PLUS++++ and the PREFERRED PLUS logo are trademarks and/or registered trademarks of Kinray Inc. All other marks are property of their respective owners.

Product Labeling

^{*}contains one or more of these ingredients



Preferred Plus Stool Softener Softgel

STOOL SOFTENER

docusate sodium capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61715-081
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	100 mg	

Inactive Ingredients			
Ingredient Name	Strength		
D&C RED NO. 33 (UNII: 9DBA0SBB0L)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
GELATIN (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6A3C0OX)			
LECITHIN, SO YBEAN (UNII: 1DI56QDM62)			
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SORBITAN (UNII: 6O92ICV9RU)			
SORBITOL (UNII: 506T60A25R)			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)			

Product Characteristics				
Color	RED, WHITE	Score	no score	
Shape	OVAL	Size	12mm	
Flavor		Imprint Code	P10;S78;SCU2	
Contains				

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
NDC:61715-081- 51	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2013	
NDC:61715-081- 57	250 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2013	
NDC:61715-081- 99	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2013	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	09/30/2013	

Labeler - Preferred Plus (Kinray) (012574513)

Revised: 11/2019 Preferred Plus (Kinray)