

STOOL SOFTENER PLUS STIMULANT LAXATIVE- docusate sodium, sennosides tablet 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 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 a bowel movement within 6 to 12 hours

Warnings

Do not use

- laxative products for longer than 1 week unless directed by a doctor
- if you are now 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 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 may indicate 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 over	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 tablets 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); excursions permitted between 15-30°C (59-86°F)

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*, silicon dioxide, sodium benzoate*, stearic acid*, talc*, titanium dioxide

*contains one or more of these ingredients

Questions or comments?

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

Principal Display Panel

Stool Softener

Plus Stimulant Laxative

†Compare to the Active ingredients in Peri-Colace®

Each tablet contains

Docusate sodium, 50 mg

plus Sennosides, 8.6 mg

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:

Kinray LLC.

152-35 Tenth Avenue

Whitestone, NY 11357

Product Labeling

Drug Facts (continued)	
<p>Stop use and ask a doctor if you have rectal bleeding or fail to have a bowel movement after use of a laxative.</p> <p>These may indicate a serious condition.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>	
Directions	
<p>■ Take only by mouth. Doses may be taken as a single daily dose, preferably in the evening, or in divided doses.</p>	
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	
<p>■ each tablet contains: calcium 20 mg</p> <p>■ each tablet contains: sodium 6 mg VERY LOW SODIUM</p> <p>■ store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F)</p>	
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*, silicon dioxide, sodium benzoate*, stearic acid, talc*, titanium dioxide	
*contains one or more of these ingredients	
Questions or comments?	
<p>Call 1-877-1753-3635 Monday-Friday 9AM-5PM EST</p>	

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61715-170
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)		DOCUSATE SODIUM	50 mg
SENNOSIDES (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX)		SENNOSIDES	8.6 mg
Inactive Ingredients			
Ingredient Name			Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)			
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)			

FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
TALC (UNII: 7SEV7J4R1U)	
ALUMINUM OXIDE (UNII: LM26O6933)	
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			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61715-170-51	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/31/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	05/31/2016	

Labeler - Preferred Plus (Kinray) (012574513)

Revised: 11/2019

Preferred Plus (Kinray)