

PERI-COLACE- docusate sodium - sennosides tablet, film coated
Purdue Products LP

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.

Peri-Colace

Drug Facts

Active ingredients (in each tablet)

Docusate sodium 50 mg

Sennosides 8.6 mg

Purpose

Stool softener

Stimulant laxative

Uses

- relieves 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 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	take 2-4 tablets
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over	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 10 mg, sodium 4 mg VERY LOW SODIUM**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F).

☐☐☐Keep tightly closed.

Inactive ingredients

dicalcium phosphate, FD&C Red #40 Aluminum Lake, FD&C Blue #2 Aluminum Lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, sodium benzoate, talc, and titanium dioxide

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Mfd. for: Purdue Products L.P.
Stamford, CT 06901-3431

By: Purdue Pharma, 575 Granite Court
Pickering, ON L1W 3W8, Canada
303048-0A

Peri-Colace® Tablets
NDC: 67618-106-30

Overnight Relief
That's Right For You

PERI-
COLACE®

*Stool Softener &
Stimulant Laxative*

- ✓ **Effective**
- ✓ **Reliable**
- ✓ **Comfortable**

30 TABLETS

PERI-COLACE

docusate sodium - sennosides tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:676 18-106
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
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	RED (burgundy)	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	P054
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:676 18-106-04	1 in 1 CARTON		
1		4 in 1 BLISTER PACK		
2	NDC:676 18-106-10	2 in 1 CARTON		
2		5 in 1 BLISTER PACK		
3	NDC:676 18-106-30	1 in 1 CARTON		
3		30 in 1 BOTTLE, PLASTIC		
4	NDC:676 18-106-60	1 in 1 CARTON		
4		60 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	02/08/1957	

Labeler - Purdue Products LP (141916531)

Registrant - Purdue Pharma LP (932323652)

Establishment

Name	Address	ID/FEI	Business Operations
Purdue Pharma		250955291	PACK(676 18-106) , MANUFACTURE(676 18-106)

Revised: 9/2013

Purdue Products LP