COLACE - docusate sodium capsule
Physicians Total Care, 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.

Colace 50 mg

Drug Facts
Colace 100 mg
Active ingredient (in each capsule)

Docusate sodium 100 mg

Purpose

Stool softener

Uses

- relieves occasional constipation (irregularity)
- generally produces a 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 movements 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 use of a laxative. These could be signs of a serious condition.
- you need to use a stool softener 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 capsules daily

children 2 to under 12 years of age	take 1 capsule daily
children under 2 years	ask a doctor

Other Information

- each tablet contains: **sodium 5 mg**
  VERY LOW SODIUM
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

Keep tightly closed.

Inactive ingredients

D&C Red No. 33, FD&C Red No. 40, FD&C Yellow No. 6, gelatin, glycerin, PEG 400, propylene glycol, sorbitol, titanium dioxide

Dist. by: **Purdue Products L.P.**
Stamford, CT 06901-3431

302112-0B

Additional bar code label applied by:
Physicians Total Care, Inc.
Tulsa, Oklahoma 74146

Colace

100mg
NDC 54868-2337-2

30 capsules

COLACE
docusate sodium capsule

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54868-2337(NDC:67618-101)
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)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
gelatin (UNII: 2G86QN327L)	
glycerin (UNII: PDC6A3C0OX)	
polyethylene glycol 400 (UNII: B697894SGQ)	
propylene glycol (UNII: 6DC9Q167V3)	
sorbitol (UNII: 506T60A25R)	
titanium dioxide (UNII: 15FIX9V2JP)	

Product Characteristics

Color	RED (Two-toned- opaque light beige and clear red)	**Score**	no score
Shape	OVAL	**Size**	1mm
Flavor		**Imprint Code**	RPC;053
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-2337-2	1 in 1 CARTON		
1		30 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	11/08/2011	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel