COLACE- docusate sodium capsule
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.

Drug Facts

Colace 50 mg

Active ingredient (in each capsule):

Docusate sodium 50 mg

Purpose

Stool softener

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 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 1-6 capsules daily
children 2 to under	take 1-3 capsules

12 years of age	daily
children under 2 years	ask a doctor

Other information

- each capsule contains: **sodium 3 mgVERY 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, gelatin, glycerin, PEG 400, propylene glycol, sorbitol

Dist. by: **Purdue Products L.P.**
Stamford, CT 06901-3431
302525-0C

Drug Facts

Colace 100 mg

Active ingredient (in each capsule):

Docusate sodium 100 mg

Purpose

Stool softener

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 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 capsules daily
children under 2 years	ask a doctor

Other information

- each capsule 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
302528-0C

Colace 50 mg 30 Capsules Carton

Colace 100 mg 30 Capsules Carton

COLACE

docusate sodium capsule

Product Information			
Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:67618-100
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Docusate sodium (docusate)	Docusate sodium	50 mg

Inactive Ingredients	
Ingredient Name	**Strength**
D&C RED NO. 33	
FD&C RED NO. 40	
GELATIN	
GLYCERIN	
POLYETHYLENE GLYCOL 400	
PROPYLENE GLYCOL	

SORBITOL	

Product Characteristics			
Color	RED	**Score**	no score
Shape	OVAL	**Size**	1mm
Flavor		**Imprint Code**	RPC;052
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67618-100-30	1 in 1 CARTON		
1		30 in 1 BOTTLE, PLASTIC		
2	NDC:67618-100-60	1 in 1 CARTON		
2		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	01/30/1997	

COLACE

docusate sodium capsule

Product Information			
Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:67618-101
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Docusate sodium (docusate)	Docusate sodium	100 mg

Inactive Ingredients

Ingredient Name	Strength
D&C RED NO. 33	
FD&C RED NO. 40	
GELATIN	
GLYCERIN	
POLYETHYLENE GLYCOL 400	
PROPYLENE GLYCOL	
SORBITOL	

Product Characteristics			
Color	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:67618-101-10	1 in 1 CARTON		
1		10 in 1 BLISTER PACK		
2	NDC:67618-101-30	1 in 1 CARTON		
2		30 in 1 BOTTLE, PLASTIC		
3	NDC:67618-101-60	1 in 1 CARTON		
3		60 in 1 BOTTLE, PLASTIC		
4	NDC:67618-101-52	250 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	01/30/1997	

Labeler - Purdue Products LP (141916531)

Registrant - Purdue Pharma LP (932323652)

Establishment

Name	Address	ID/FEI	Business Operations
Catalent Pharma Solutions, LLC		051762268	MANUFACTURE(67618-101, 67618-100)

Establishment

Name	Address	ID/FEI	Business Operations
PL Developments		800014821	PACK(67618-100, 67618-101)

Revised: 11/2012 Purdue Products LP