COLACE- docusate sodium capsule
Atlantis Consumer Healthcare, Inc.

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 todo 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 over2 weeks

Stop use and ask a doctor if

- you have rectal bleeding or fail to have a bowel movementafter use of a laxative. These could be signs of a serious condition.
- you need to use a stool softener laxative for more than1 week

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In caseof overdose, get medical help or contact a Poison Control Center rightaway.

Directions: Take only by mouth. Dosesmay be taken as a single daily dose or in divided doses.

adults and children 12 yearsand over	take 1-3 capsules daily
children 2 to under 12 yearsof age	take 1 capsules daily
children under 2 years	ask a doctor

Otherinformation

- 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 Blue #1, FD&C Red No. 40, FD&C Yellow No. 6, gelatin, glycerin, PEG 400, propylene glycol, sorbitol, titanium dioxide

Avrio Health L.P.

304996-0A

Colace 100mg 100 Capsules Carton

COLACE

docusate sodium capsule

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	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)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	RED, WHITE	**Score**	no score
Shape	OVAL	**Size**	12mm
Flavor		**Imprint Code**	RPC;053
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67618-101-10	2 in 1 CARTON	01/30/1997	
1		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:67618-101-30	1 in 1 CARTON	01/30/1997	
2		30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:67618-101-60	1 in 1 CARTON	01/30/1997	
3		60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:67618-101-01	1 in 1 CARTON	01/17/2022	
4		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
5	NDC:67618-101-52	250 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/30/1997	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	01/30/1997	

Labeler - Atlantis Consumer Healthcare, Inc. (118983925)

Registrant - Atlantis Consumer Healthcare, Inc. (118983925)

Revised: 12/2023

Atlantis Consumer Healthcare, Inc.