

COLACE- docusate sodium capsule
REMEDYREPACK 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.

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 Blue #1, FD&C Red No. 40,

FD&C Yellow No. 6, gelatin, glycerin, PEG

400, propylene glycol, sorbitol, titanium

dioxide

Repackaged and Distributed By:

Remedy Repack, Inc.

625 Kolter Dr. Suite #4 Indiana, PA 1-724-465-8762

DRUG: Colace

GENERIC: Docusate sodium

DOSAGE: CAPSULE

ADMINISTRATION: ORAL

NDC: 70518-3319-0

COLOR: red

SHAPE: OVAL

SCORE: No score

SIZE: 12 mm

IMPRINT: RPC;053

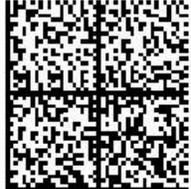
PACKAGING: 30 in 1 BLISTER PACK

ACTIVE INGREDIENT(S):

- Docusate sodium 100mg in 1

INACTIVE INGREDIENT(S):

- D&C RED NO. 33
- FD&C RED NO. 40
- GELATIN
- GLYCERIN
- POLYETHYLENE GLYCOL 400
- PROPYLENE GLYCOL
- SORBITOL
- FD&C BLUE NO. 1
- FD&C YELLOW NO. 6
- TITANIUM DIOXIDE

<h1>Colace</h1> <p>Docusate Sodium</p> <p>100 mg</p> <p>Capsule</p> <p>QTY: 30</p> <p>Stool Softener</p> 	<p>NDC #: 70518-3319-00</p> <p>Expires:</p> <p>LOT #:</p> <p>Source NDC: 67618-0101-60</p> <p>MFG: Avrio Health L.P., Stamford, CT 06901-3431</p> <p>Keep this and all medication out of the reach of children</p>	
<p>Directions For Use: See Package Insert</p> <p>Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F) [See USP]</p> <p>Repackaged by: RemedyRepack Inc., Indiana, PA 15701, 724.465.8762</p> <p style="text-align: right;">NOT FOR RETAIL SALE</p>		

COLACE			
docusate sodium capsule			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70518-3319(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:70518-3319-0	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	12/29/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	12/29/2021	

Labeler - REMEDYREPACK INC. (829572556)

Revised: 1/2022

REMEDYREPACK INC.