# STOOL SOFTENER LAXATIVE- docusate sodium capsule, liquid filled Rite Aid Corporation

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.

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#### **Drug Facts**

#### Active ingredient (in each softgel)

Docusate sodium 100 mg

#### **Purpose**

Stool softener laxative

#### 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
- a sudden change in bowel habits that lasts over 14 days

### 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 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 (1-800-222-1222) right away.

#### **Directions**

take only be mouth. Doses may be taken as a single daily dose or in divided doses.

adult and children 12 years and over	take 1-3 softgels daily
children 2 to under 12 years of age	take 1 softgel daily
children under 2 years	ask a doctor

#### Other information

- each softgel contains:sodium 6 mg
- store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F)

#### Inactive ingredients

black iron oxide, D&C red #33, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, glycerin, hypromellose, polyethylene glycol, propylene glycol, purified water, sorbitan, sorbitol, titanium dioxide

#### Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

# **Principal Display Panel**

Compare to the active ingredient in Colace® Regular Strength Stool Softener\*

REGULAR STRENGTH

#### STOOL SOFTENER

#### COL•RITE

DOCUSATE SODIUM 100 mg

STOOL SOFTENER LAXATIVE

Gentle • Dependable

Stimulant-free

**SOFTGELS** 

†This product is not manufactured or distributed by Avrio Health L.P., distributor of Colace® Regular Strength Stool Softener

# TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

**DISTRIBUTED BY:** 

RITE AID, 200 NEWBERRY COMMONS ETTERS, PA 17319

#### **Product Label**



**RITE AID Regular Strength Stool Softener** 

# STOOL SOFTENER LAXATIVE docusate sodium capsule, liquid filled Product Information Product Type HUMAN OTC DRUG Item Code (Source) Route of Administration ORAL Active Ingredient/Active Moiety

Ingredient Name	<b>Basis of Strength</b>	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 BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
GELATIN (UNII: 2G86QN327L)		
GLYCERIN (UNII: PDC6A3C0OX)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SORBITAN (UNII: 6092ICV9RU)		
SORBITOL (UNII: 506T60A25R)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
FERROSOFERRIC OXIDE (UNII: XM0M87F357)		

Product Characteristics			
Color	red, white	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	P10
Contains			

Packaging				
# Ite	em Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC 001	C:11822- 7-8	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/31/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	12/31/2020	

# Labeler - Rite Aid Corporation (014578892)

Revised: 9/2023 Rite Aid Corporation