STOOL SOFTENER LAXATIVE- docusate sodium capsule, liquid filled EQUALINE (SuperValu)

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

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 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 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 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 softgels dailychildren 2 to under 12 years of agetake 1 softgel dailychildren under 2 yearsask a doctor

Other information

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

Inactive ingredients

ammonium hydroxide, anhydrous citric acid, D&C red #33, ethyl alcohol, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, glycerin, isopropyl alcohol, lecithin, mineral oil, n-butyl alcohol, polyethylene glycol, potassium hydroxide, propylene glycol, purified water, sorbitan, sorbitol, titanium dioxide

Questions or comments?

Call toll free 1-855-423-2630

Principal Display Panel

compare to Colace® Regular Strength Stool Softener active ingredient†

Stool Softener

docusate sodium 100 mg

Stool softener laxative

relieves constipation

softgels

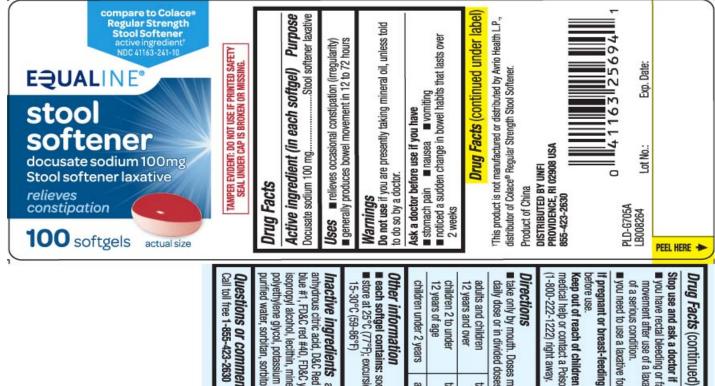
†This product is not manufactured or distributed by Avrio Health L.P., distributor of Colace® Regular Strength Stool Softener.

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

DISTRIBUTEDBY UNFI

PROVIDENCE, RI 02908 USA

Product Label



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r breast-feedin reach of childrer or contact a Pois 222) right away	vr breast-feeding, ask a health professional reach of children. In case of overdose, get or contact a Poison Control Center (222) right away.
S y mouth. Doses ma or in divided doses.	S y mouth. Doses may be taken as a single or in divided doses.
children 1d over	take 1-3 softgels daily
to under Fage	take 1 softgel daily
der 2 years	ask a doctor
ormation gel contains: °C (77°F); excu 19-86°F)	ormation ger contains: sodium 5 mg °C (77°F); excursions permitted between 19-86°F)
ngredients tric acid, D&C R C red #40, FD&C bhol, lecithin, mi glycol, potassiu glycol, potassiu	ingredients ammonium hydroxide, rric acid, D&C Red #33, ethyl alcohol, FD&C C red #40, FD&C yellow # 6, gelatin, glycerin, bhol, lecithin, mineral oil, n-butyl alcohol, glycol, potassium hydroxide, propylene glycol, r, sorbitan, sorbitol, titanium dioxide
s or comments? 1-855-423-2630	ents?

EQUALINE Stool Softener Laxative

STOOL SOFTENER L	ΑΧΑΤΙνε				
docusate sodium capsule, lic	luid filled				
Product Information					
Product Type	HUMAN OTC DRUG	ltem Code (So	urce)	NDC:411	63-241
Route of Administration	ORAL				
Active Ingredient/Active	Moiety				
Ingr	edient Name		Basis of St	rength	Strength
DOCUSATE SODIUM (UNII: F05Q2	2T2JA0) (DOCUSATE - UNII:M	7P27195AG)	DOCUSATE SO	DIUM	100 mg
Inactive Ingredients					
	Ingredient Name			S	trength
D&C RED NO. 33 (UNII: 9DBA0SB	BOL)				
FD&C BLUE NO. 1 (UNII: H3R47K	3TBD)				
FD&C RED NO. 40 (UNII: WZB912	27XOA)				
FD&C YELLOW NO. 6 (UNII: H77'	VEI93A8)				

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)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ALCOHOL (UNII: 3K9958V90M)	
AMMONIA (UNII: 5138Q19F1X)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MINERAL OIL (UNII: T5L8T28FGP)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
POTASSIUM HYDROXIDE (UNII: WZ H3C48M4T)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	

Product Characteristics

Color	red, white	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	PC18
Contains			

Packaging

1NDC:41163- 241-20200 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product03/26/20212NDC:41163- 241-10100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product03/26/2021	#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:41163- 241-20		03/26/2021	
				03/26/2021	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC monograph not final	part334	03/26/2021	

Labeler - EQUALINE (SuperValu) (006961411)

Revised: 11/2022

EQUALINE (SuperValu)