STOOL SOFTENER- docusate sodium capsule, liquid filled EQUATE (Wal-Mart Stores, 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

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
- 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 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 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

D&C red #33, edible ink, FD&C blue #1*, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol*, purified water, sorbitan, sorbitol, titanium dioxide

*contains one or more of these ingredients

Questions or comments?

1-888-287-1915

Principal Display Panel

Compare to Colace® Regular Strength Stool Softener Active Ingredient†

Stool Softener

Docusate Sodium, 100mg

Stool Softener Laxative

- Gentle
- Dependable
- Stimulant-free

SOFTGELS

†This product is not manufactured or distributed by Purdue Products 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: Wal-Mart Inc.,

Bentonville, AR 72716

Product Label



EQUATE Stool Softener Laxative

STOOL SOFTENER

docusate sodium capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-078
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
DO CUSATE SO DIUM (UNII: F05Q2T2JA0) (DO CUSATE - 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: PDC6 A3C0 OX)			

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

Product Characteristics			
Color	RED, WHITE	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	P10;SCU2;D1
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:49035-078- 14	140 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/31/2017		
2	NDC:49035-078- 28	280 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/31/2017		
3	NDC:49035-078- 41	140 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/31/2017		
4	NDC:49035-078- 60	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/31/2017		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	12/31/2017	

Labeler - EQUATE (Wal-Mart Stores, Inc.) (051957769)

Revised: 6/2019 EQUATE (Wal-Mart Stores, Inc.)