STOOL SOFTENER- docusate sodium capsule, liquid filled EQUATE (Walmart 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 Ingredients (in each softgel)

Docusate Sodium 100 mg

Purpose

Stool softener

Uses

- relieves occasional constipation (irregularity)
- generally produces a 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 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 of age	ask a doctor

Other information

• each softgel contains: sodium 6 mg

• store at controlled room temperature 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, sorbitol special, titanium dioxide.

Questions or comments?

1-888-287-1915

Principal Display Panel

Compare to the active ingredient in Colace® *

Stool Softener

Docusate Sodium, 100 mg

- Relieves constipation
- Gentle and effective
- Stimulant free for comfortable relief

*This product is not manufactured or distributed by Purdue Products L.P., owner of the registered trademark Colace®

Gluten free

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION Satisfaction guaranteed- for questions or comments please call 1-888-287-1915

Product Labeling



Docusate sodium 100 mg capsules

STOOL SOFTENER docusate sodium capsule, liquid filled **Product Information** HUMAN OTC DRUG LABEL NDC:49035-111 Product Type Item Code (Source) Route of Administration ORAL **DEA Schedule**

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DOCUSATE SODIUM (DOCUSATE)	DOCUSATE SODIUM	100 mg	

Inactive Ingredients		
Ingredient Name	Strength	
D&C RED NO. 33		
FD&C BLUE NO. 1		
FD&C RED NO. 40		
FD&C YELLOW NO. 6		
GELATIN		
GLYCERIN		
POLYETHYLENE GLYCOLS		
PROPYLENE GLYCOL		
WATER		
SORBITOL		
TITANIUM DIO XIDE		

Product Characteristics			
Color	RED, WHITE	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	P10;51A
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:49035-111-06	1 in 1 BOX		
1	60 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	0 3/0 1/20 12	

Labeler - EQUATE (Walmart Stores, Inc.) (051957769)

 $\pmb{Registrant - P \text{ and L Development of New York Corporation (800014821)}}$

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