QUALITY CHOICE STOOL SOFTENER- docusate sodium capsule, liquid filled Chain Drug Marketing Association

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.

DOCUSATE SODIUM 100mg Two-Tone, Capsule, liquid filled Drug Facts

Active ingredient (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 movements 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.

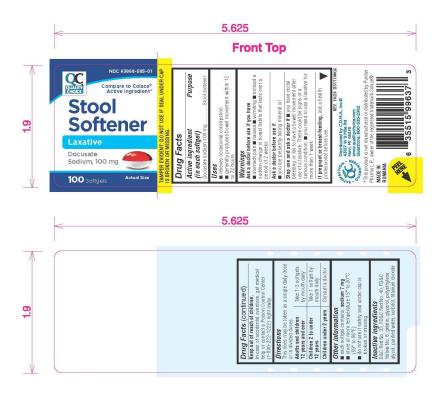
adults and children 12 years and over	take 1 to 3 softgels daily
children 2 to under 12 years of age	take 1 softgel daily
children under 2 years	ask a doctor

Other information

- each softgel contains: **sodium 5 mg**
- VERY LOW SODIUM
- store at room temperature 15°-30°C (59°-86°F) and avoid excessive heat

Inactive Ingredients

D&C Red No. 33, FD&C Red No. 40, FD&C Yellow No. 6, gelatin, glycerol, Polyethylene glycol, purified water, sorbitol, titanium dioxide



QUALITY CHOICE STOOL SOFTENER

docusate sodium capsule, liquid filled

Product Information

l	Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-585
ı	Poute 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		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
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)			
SORBITOL (UNII: 506T60A25R)			
WATER (UNII: 059QF0KO0R)			

Product Characteristics				
Color	red, white (Two-Tone)	Score	no score	
Shape	CAPSULE (OVAL)	Size	10mm	
Flavor		Imprint Code	SCU2	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:63868-585- 01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/11/2020		
2	NDC:63868-585- 25	250 in 1 BOTTLE; Type 0: Not a Combination Product	11/11/2020		

Marketing Information			
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
part334	11/11/2020		
	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date	

Registrant - Reese Pharmaceutical (004172052)

Establishment				
Name	Address	ID/FEI	Business Operations	
Swiss Caps Romania		565466997	manufacture(63868-585)	

Revised: 12/2022 Chain Drug Marketing Association