RITE AID STOOL SOFTENER- docusate calcium capsule, liquid filled Rite Aid

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 Calcium

Active ingredient

Docusate Calcium 240 mg

Purpose

Stool Softener

Uses

- For the relief of occasional constipation.
- This product generally produces a bowel movement within 12 to 72 hours.

Warnings: Do not use

- If you are currently taking mineral oil, unless directed by a doctor.
- When abdominal pain, nausea or vomiting are present.
- For longer than one week unless directed by a doctor.

Ask a Doctor Before Use

■ 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.
- You fail to have a bowel movement after use.

If Pregnant or Breast Feeding

Ask a healthcare professional before use.

Keep Out of Reach of Children.

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

Adults and Children over 12 years of age

Take orally 1 softgel daily for 2 to 3 days or until bowl movements are normal, or as directed by a doctor.

Children under 12 years of age

Do not use this product for children under 12 years of age, unless directed by a doctor.

Other Information

- Store at room temperature between 15°C to 25°C (59°F to 77°F).
- Do not use if either seal is broken or missing.

Inactive Ingredients

FD&C Blue #1, FD&C Red #40, Gelatin, Glycerin, Sorbitol Special.

Questions or Comments

Package/Label Principal Display Panel



RITE AID STOOL SOFTENER

docusate calcium capsule, liquid filled

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-7810	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DOCUSATE CALCIUM (UNII: 6K7YS503HC) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE CALCIUM	240 mg	

Inactive Ingredients			
Ingredient Name	Strength		
GELATIN (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6A3C0OX)			
SORBITOL (UNII: 506T60A25R)			
WATER (UNII: 059QF0KO0R)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			

Product Characteristics				
Color	red	Score	no score	
Shape	OVAL	Size	19mm	
Flavor		Imprint Code	SCU	
Contains				

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:11822- 7810-0	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/05/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	11/22/2021	

Labeler - Rite Aid (014578892)

Registrant - Reese Pharmaceutical Co (004172052)

Establishment			
Name	Address	ID/FEI	Business Operations

Swiss Caps Romania	565466997	manufacture(11822-7810)

Revised: 12/2022 Rite Aid