PREFERRED STOOL SOFTENER- docusate calcium capsule, liquid filled
Reese Pharmaceutical Co

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 15ºC to 25ºC (59ºF to 77ºF).
- 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

PREFERRED STOOL SOFTENER

docusate calcium capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10956-891
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			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10956-891-00	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	05/11/2023	

Labeler - Reese Pharmaceutical Co (004172052)

Registrant - Reese Pharmaceutical Co (004172052)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss Caps Romania		565466997	manufacture(10956-891)

Revised: 5/2023 Reese Pharmaceutical Co