

**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 bowel 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

Preferred
Stool Softener
Docusate Calcium, 240 mg | Laxative
Gentle Relief of Constipation
✓ Once-a-Day Dosage
✓ Sodium Free
100 SOFTGELS
Actual Size

TAMPER EVIDENT: DO NOT USE IF SEAL UNDER CAP IS BROKEN OR MISSING.

Drug Facts
Active ingredient (in each softgel) Purpose
Docusate Calcium 240 mg Stool Softener

Uses ■ for relief of occasional constipation
■ this product generally produces bowel movement within 12 to 72 hours

Warnings
Do not use ■ if you are currently taking mineral oil, unless directed 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

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
This dose may be taken as a single daily dose or in divided doses.
■ Adults and children 12 years and over: take 1 softgel daily or as directed by a doctor. ■ Children under 12 years of age: ask a doctor.

Other information ■ store at 20°-25°C (68° to 77°F); excursions permitted between 15°-30° (59° to 86°F)

Inactive ingredients D&C RED NO. 33 POWDER, FD&C BLUE #1 POWDER, FD&C RED #40, GELATIN, GLYCEROL, SORBITOL, PURIFIED WATER.

Questions? 1-800-321-7178

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MADE IN ROMANIA
REV. 4/23 D0CC100R

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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