

DOCUSATE SODIUM 100MG TWO-TONE- docusate sodium capsule, liquid filled
Discount Drug Mart, 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.

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

Compare to Colace®
Active Ingredient*

Stool Softener

Laxative

Docusate Sodium, 100 mg

- Gentle
- Dependable
- Stimulant-Free

250 Softgels



Actual Size

NDC XXXXX-XXX-XX

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

Drug Facts

<i>Active ingredients (in each softgel)</i>	<i>Purpose</i>
Docusate sodium 100 mg.....	Stool softener

Uses

- relieves occasional constipation
- generally produces bowel movement within 12 to 72 hours

Warnings

Ask a doctor before use if you have

- stomach pain ■ nausea ■ vomiting ■ noticed a sudden change in bowel habits that lasts over a period of 2 weeks

Ask a doctor before use if

- you are presently taking mineral oil

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

Signs of a serious condition — you need to use laxatives 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 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 1-3 softgels by mouth daily
Children 2 to under 12 years	Take 1 softgel by mouth daily
Children under 2 years	Consult a doctor

Other information ■ each softgel contains: **sodium 7 mg**
 ■ store at room temperature 15° to 30°C (59° to 86°F)
 ■ do not use if safety seal under cap is broken or missing.

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

Distributed By:

REV. X/XX REESE CODE

MADE IN ROMANIA



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

DOCUSATE SODIUM 100MG TWO-TONE

docusate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53943-250
Route 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	10 mm
Flavor		Imprint Code	SCU2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53943-250-25	1 in 1 CARTON	12/23/2019	
1		250 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:53943-250-10	1 in 1 CARTON	12/23/2019	
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	12/23/2019	

Labeler - Discount Drug Mart, Inc (047741335)

Registrant - Reese Pharmaceutical (004172052)

Establishment

Name	Address	ID/FEI	Business Operations
Reese Pharmaceutical		004172052	relabel(53943-250) , repack(53943-250)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss Caps Romania		565466997	manufacture(53943-250)

