STOOL SOFTENER LAXATIVE- docusate calcium capsule, liquid filled Major Pharmaceuticals

Drug Facts

Active ingredient (in each softgel)

Docusate calcium 240 mg

Purpose

Stool softener laxative

Uses

- for relief of occasional constipation (irregularity)
- 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.

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

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

- adults and children 12 years of age and over: take 1 softgel daily or as directed by a doctor
- children under 12 years of age: ask a doctor

Other information

• store between 20-25°C (68-77°F); excursions permitted between 15-30°C (59-86°F)

Inactive ingredients

corn oil, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, glycerin, purified water, sorbitan, sorbitol

Questions or comments?

Call **1-800-616-2471**

Principal Display Panel

Compare to the active ingredient in Surfak®†

Docusate Calcium

240 mg

Stool Softener Laxative

Sodium Free

Softgels

†This product is not manufactured or distributed by Chattem, Inc., distributor of Surfak®.

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by:

MAJOR® PHARMACEUTICALS

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152

Product Label



NDC 0904-6997-60

Compare to the active ingredient in Surfak^{et}



NDC 0904-6997-60

Compare to the active ingredient in Surfak^{et}

Docusate Calcium

240 mg

Stool Softener Laxative Sodium Free

100 Softgels

Distributed by: MAJOR® PHARMACEUTICALS 17177 N Laurel Park Drive, Suite 233 Livonia, MI 48152

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Rev. 10/19 M-58 Re-order No. 701187

PLD-A609A FC006263

Lot No.: Exp. Date:

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MAJOR Stool Softener Laxative

STOOL SOFTENER LAXATIVE

docusate calcium capsule, liquid filled

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0904-6997

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			
CORN OIL (UNII: 8470G57WFM)				
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)				
WATER (UNII: 059QF0KO0R)				
SORBITOL (UNII: 506T60A25R)				
SORBITAN (UNII: 6O92ICV9RU)				

Product Characteristics						
Color	red	Score	no score			
Shape	CAPSULE	Size	18mm			
Flavor		Imprint Code	SCU			
Contains						

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:0904- 6997-60	1 in 1 BOX	09/30/2019	02/28/2026		
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product				
2	NDC:0904- 6997-80	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2019	02/28/2026		
3	NDC:0904- 6997-40	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2019	02/28/2026		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M007	09/30/2019	02/28/2026		

Labeler - Major Pharmaceuticals (191427277)

Revised: 7/2025 Major Pharmaceuticals