

DOCUSATE SODIUM- docusate sodium capsule

Major Pharmaceuticals

Drug Facts

Active ingredient (in each softgel)

Docusate Sodium 100 mg

Purpose

Stool softener laxative

Uses

- relieves occasional constipation (irregularity)
- generally produces 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 habits that last 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 a 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 (1-800-222-1222) 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
- store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F)

Inactive ingredients

edible ink, FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water sorbitan, sorbitol

Questions or comments?

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

Principal Display Panel

Compare to the active ingredient in Colace® Regular Strength Stool Softener†

Docusate sodium 100 mg

Stool Softener Laxative

Softgels

†This product is not manufactured or distributed by Avrio Health L.P., distributor of Colace® Regular Strength Stool Softener.

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

Distributed by:

MAJOR® PHARMACEUTICALS

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152

Product Label

MAJOR

NDC 0904-6998-80
Compare to the active ingredient in Colace® Regular Strength Stool Softener†

Docusate Sodium

100 mg

Stool Softener Laxative

1000 Softgels



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Rev. 05/20 M-58 Re-order No. 70189



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

Exp. Date:

Lot No.:

MAJOR PHARMACEUTICALS Stool Softener Laxative

DOCUSATE SODIUM docusate sodium capsule			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-6998
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	
FD&C RED NO. 40 (UNII: WZB9127XOA)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
GELATIN (UNII: 2G86QN327L)			
SORBITAN (UNII: 6O921CV9RU)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SORBITOL (UNII: 506T60A25R)			
GLYCERIN (UNII: PDC6A3C0OX)			
Product Characteristics			
Color	orange	Score	no score

Shape	OVAL	Size	12mm
Flavor		Imprint Code	P51
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6998-60	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/28/2020	
2	NDC:0904-6998-80	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	02/28/2020	

Labeler - Major Pharmaceuticals (191427277)

Revised: 4/2024

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