DOCUSATE SODIUM - STOOL SOFTENER LAXATIVE- docusate sodium capsule, liquid filled
Major Pharmaceuticals

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 - Stool Softener Laxative

Drug Facts

Active ingredient (in each softgel)

Docusate Sodium 100 mg

Purpose

Stool softener laxative

Uses

• for relief of occasional constipation (irregularity)
• This generally produces a bowel movement within 12 to 72 hours.

Warnings

Ask a doctor before use if you have
• abdominal pain, nausea, or vomiting
• a sudden change in bowel habits that lasts over 14 days

Ask a doctor or pharmacist before use if you are presently taking mineral oil

Stop use and ask a doctor if
• you have rectal bleeding or no bowel movement after using this product.
These can 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 care professional before use.

Keep out of reach of children
Overdose Warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

Directions

• take softgels with a full glass (8 oz) of water

adults and children 12 years of age and older	take 1 to 3 softgels daily or as directed by a doctor. This dose may be taken as a single daily dose or in divided doses.
children 6 to under 12 years of age	take 1 softgel daily or as directed by a doctor
children under 6 years of age	ask a doctor

Other information

- **each softgel contains:** sodium 10 mg (very low sodium)
- store at 25°C (77°F) in a dry place. Avoid excessive heat 40°C (140°F).

Inactive ingredients

edible white ink, FD&C red no. 40, FD&C yellow no. 6, gelatin, glycerin, isopropyl alcohol, light mineral oil, medium chain triglycerides, polyethylene glycol, propylene glycol, purified water, sorbitol sorbitan solution

Questions or comments?

(800)616-2471

MAJOR®

Unit Dose

READ AND KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Distributed by:
MAJOR® PHARMACEUTICALS
Livonia, MI 48152

Product of UAE
Packaged and Quality Assured in the USA

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

Packaging

DRUG FACTS LABEL

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Drug Facts (continued)

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Questions or comments? (800)616-2471

DOCUSATE SODIUM - STOOL SOFTENER LAXATIVE

docusate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0904-7183
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, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	red	**Score**	no score
Shape	OVAL	**Size**	12mm
Flavor		**Imprint Code**	777
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-7183-61	10 in 1 CARTON	09/04/2021	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC monograph not final	part334	09/04/2021	

Labeler - Major Pharmaceuticals (191427277)

Revised: 7/2023 Major Pharmaceuticals