

DOCUSATE SODIUM, EXTRA STRENGTH 250 MG- docusate sodium capsule, gelatin coated
Advanced Rx LLC

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.

Advanced Rx - PUREGEN - DOCUSATE SODIUM 250MG (80513-100)

ACTIVE INGREDIENT (IN EACH SOFTGEL)

DOCUSATE SODIUM 250 MG

PURPOSE

Stool softener laxative

USES

- for the prevention of dry, hard stools
- for relief of occasional constipation
- this product generally produces a bowel movement within 12 to 72 hours

WARNINGS

Do not use if you are presently 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 (1-800-222-1222) 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

- each softgel contains: sodium 20 mg
- store at 20°- 25°C (68°- 77°F); excursions permitted between 15°-30°C (59°-86°F)

INACTIVE INGREDIENTS

edible ink, FD&C red #40, FD&C yellow #6, gelatin (bovine), glycerin, polyethylene glycol, purified water, sorbitol special.

QUESTIONS?

call 1-800-630-8895

**PUREGEN
LABS**

Extra Strength

**Docusate
Sodium**

250 mg

Stool Softener Laxative

100 Softgels

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Drug Facts

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Docusate sodium 250 mg.....	Stool softener laxative

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Distributed by: Advanced Rx, 1942 NE 163rd St
North Miami Beach, FL 33162 U.S.A.

L9042-100-106-0

DOCUSATE SODIUM, EXTRA STRENGTH 250 MG

docusate sodium capsule, gelatin coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80513-100
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	250 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
GELATIN TYPE B BOVINE (160 BLOOM) (UNII: 1T8387508X)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

WATER (UNII: 059QF0KO0R)

SORBITOL SOLUTION (UNII: 8KW3E207O2)

Product Characteristics

Color	red	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	SCU1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80513-100-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/15/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	09/15/2022	

Labeler - Advanced Rx LLC (042795108)

Revised: 5/2023

Advanced Rx LLC