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

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

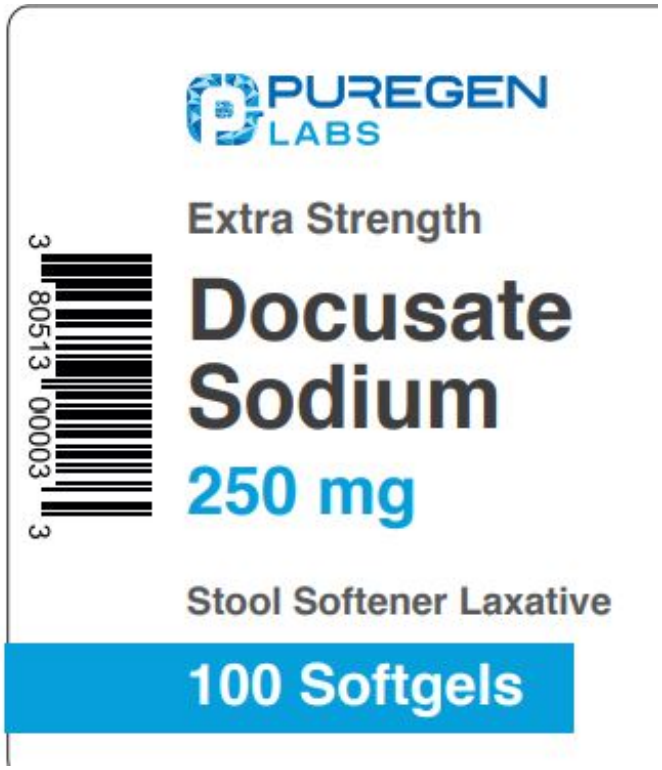
- each softgel contains: sodium 20 mg
- store at 20°- 25°C (68°- 77°F); excursions permitted between 15°-30°C (59°-86°F)

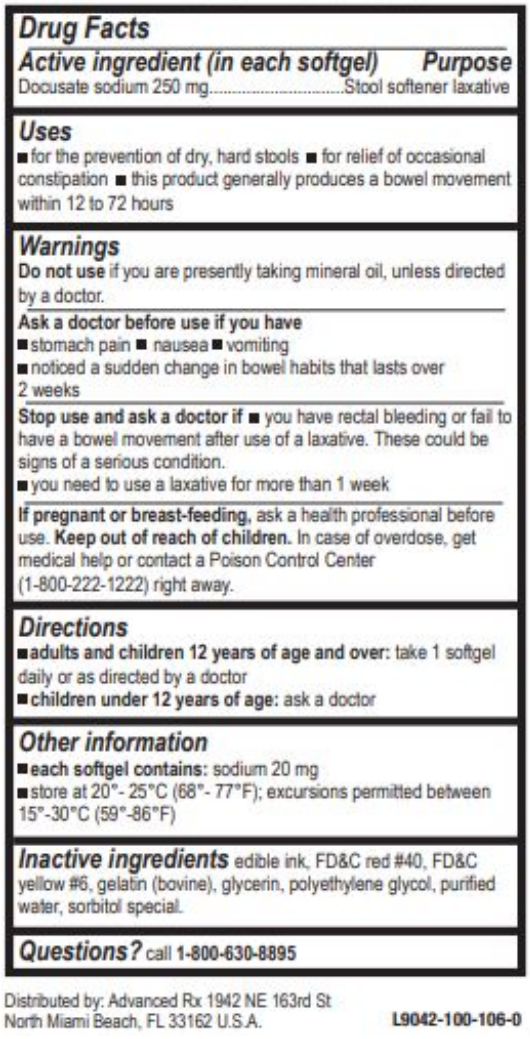
INACTIVE INGREDIENTS

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





Drug Facts

Active ingredient (in each softgel) **Purpose**
Docusate sodium 250 mg.....Stool softener laxative

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Questions? call **1-800-630-8895**

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: 3WQ0SDW1A)	

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 Drug	M007	09/15/2022	

Labeler - Advanced Rx LLC (042795108)

Revised: 9/2024 Advanced Rx LLC