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 (80513-101)

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

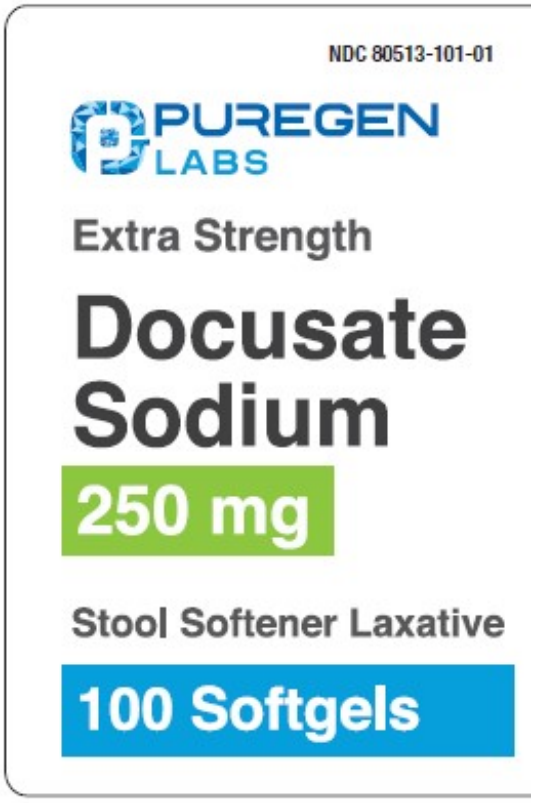
- each softgel contains: sodium 20 mg
- Phenylketonurics: Contains phenylalanine 4 mg per softgel
- store at 15°- 25°C (59°- 77°F)

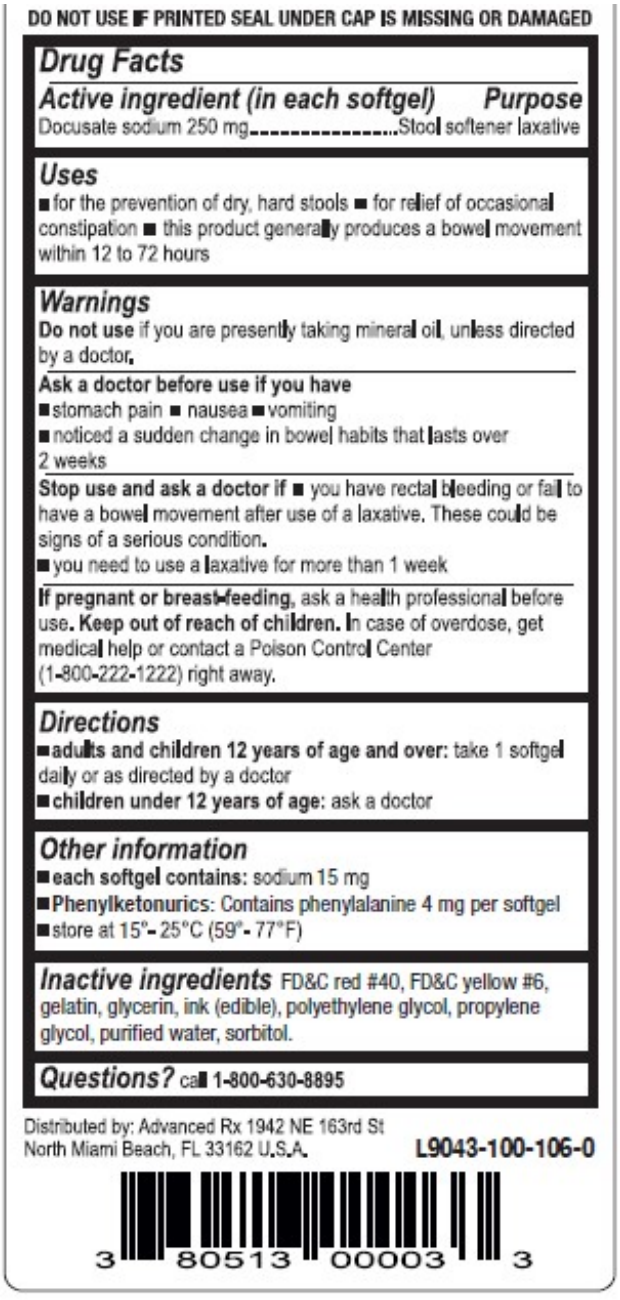
INACTIVE INGREDIENTS

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

QUESTIONS?

call 1-800-630-8895





DOCUSATE SODIUM, EXTRA STRENGTH 250 MG

docusate sodium capsule, gelatin coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80513-101
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
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
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**	21mm
Flavor		**Imprint Code**	NV12
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80513-101-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	05/25/2023	

Labeler - Advanced Rx LLC (042795108)

Revised: 5/2023 Advanced Rx LLC