DOCUSATE SODIUM- docusate sodium 100mg capsule
PHARMAMED USA INC

Docusate Sodium 100 mg Softgels

Active ingredient (in each softgel)

Docusate Sodium 100 mg

Purpose

Stool softener

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 lasts over 2 weeks

Stop use and ask a doctor if

- you have rectal bleeding or fail to have bowel movement after use of a laxative. These could be signs of a serious condition.
- you need to use a stool softener 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 right away. (1 800-222-1222)

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 1-3 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 6 mg**
- **VERY LOW SODIUM**
- store at 25ºC (77ºF); excursions permitted between 15º-30ºC (59º-86ºF).

keep tightly closed.

Inactive ingredients

D&C Red #33, edible ink, FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, polyethylene glycol, purified water, sorbitol special, titanium dioxide

Questions or comments?

(866) 562-2756 (Mon-Fri 8 AM to 4 PM EST)

Package Label Principal Display Panel

PHARMAMED

NDC 84289-399-01

Manufactured in the U.S.A

Docusate

Sodium

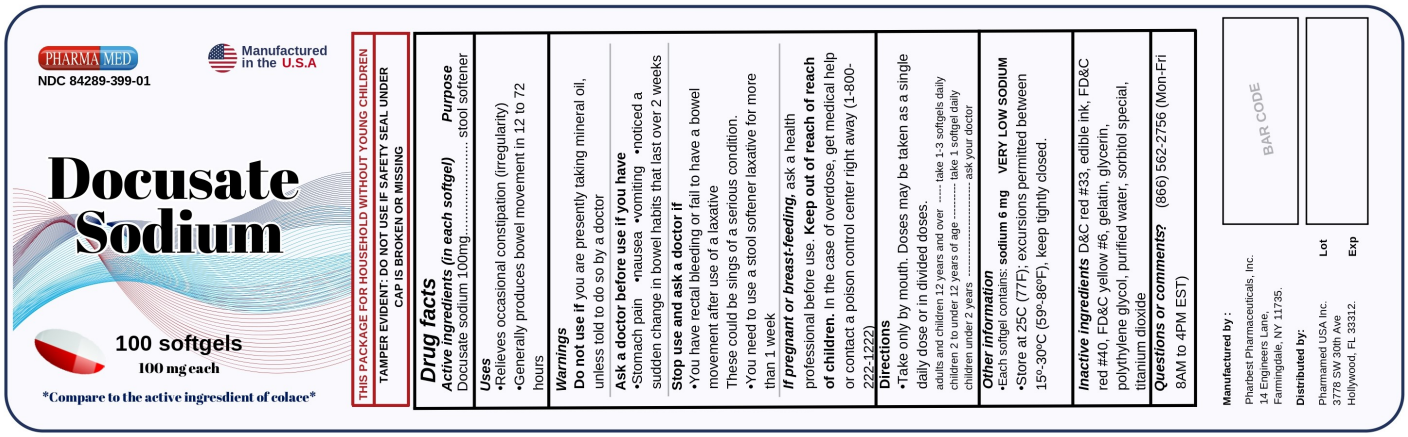
100 softgels

100mg each

Compare to the active ingredient of Colace

THIS PACKAGE FOR HOUSEHOLD WITHOUT YOUNG CHILDREN

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



DOCUSATE SODIUM

docusate sodium 100mg capsule

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:84289-399(NDC:16103-399)
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

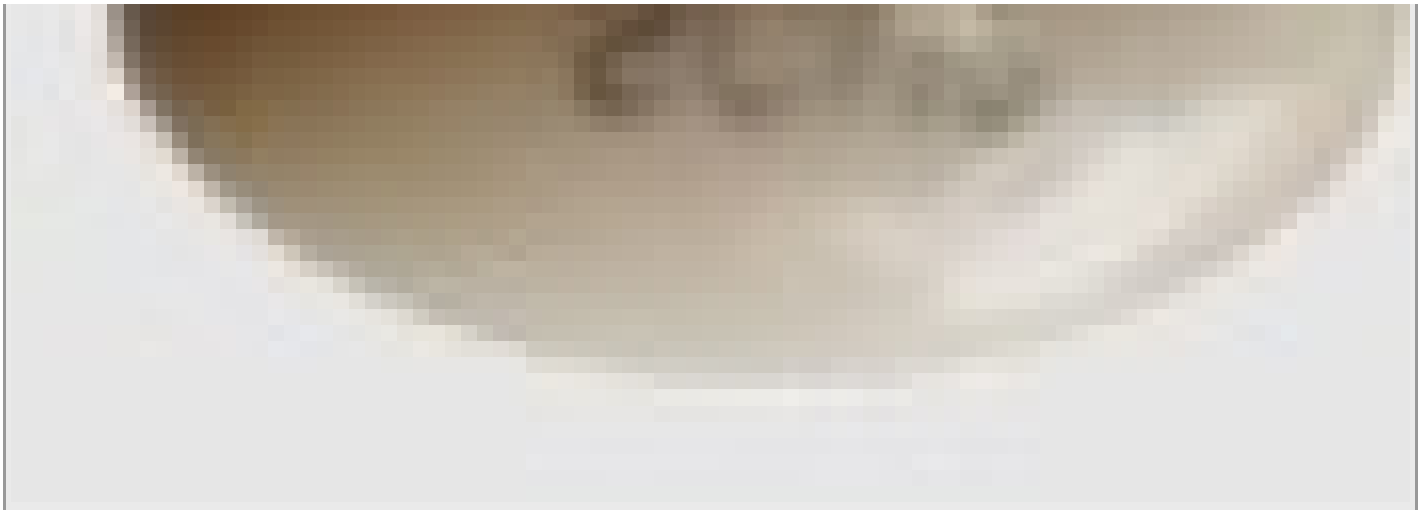
Inactive Ingredients	
Ingredient Name	**Strength**
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	

Product Characteristics			
Color	red (TWO-TONED- WHITE AND CLEAR RED)	**Score**	no score
Shape	OVAL	**Size**	12mm
Flavor		**Imprint Code**	SCU2
Contains			

Packaging

			Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84289-399-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2024	



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	10/01/2024	

Labeler - PHARMAMED USA INC (065607328)

Registrant - PHARBEST PHARMACEUTICALS, INC. (557054835)

Establishment

Name	Address	ID/FEI	Business Operations
PHARBEST PHARMACEUTICALS, INC.		557054835	repack(84289-399)

Revised: 6/2024 PHARMAMED USA INC