STOOL SOFTENER EXTRA STRENGTH- docusate sodium capsule, liquid filled
Atlantic Biologicals Corps

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.

Drug Facts

Active ingredient (in each softgel)

Docusate Sodium 250 mg

Purpose

Stool softener

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 currently taking mineral oil, unless directed by a doctor
- when abdominal pain, nausea, or vomiting are present
- for more than 1 week, unless directed by a doctor

Ask a doctor before use if

you notice a sudden change in bowel habits that persists over a period of 2 weeks

Stop use and ask a doctor if

- you have rectal bleeding
- you fail to have a bowel movement after use

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.

Directions

- take 1 softgel daily or as directed by a doctor **adults and children over 12 years of age and over:**
- : take as directed by a doctor **children under 12 years of age**

Other information

- sodium 15 mg **each softgel contains:**
- store at controlled room temperature 15 - 30 C (59 - 86 F) oooo
- do not use if imprinted safety seal under cap is broken or missing

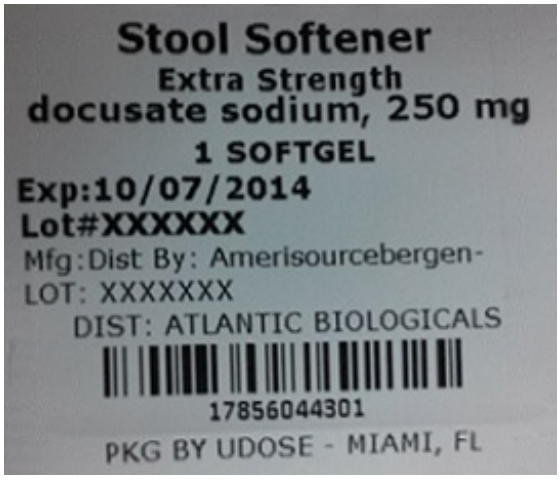
Inactive Ingredients

edible white ink, FD&C Red No# 40, FD&C Yellow No# 6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water and sorbitol special.

Questions or comments?

Call toll free **1-877-753-3935**

STOOL SOFTENER EXTRA STRENGTH (DOCUSATE SODIUM) CAPSULE, LIQUID FILLED



STOOL SOFTENER EXTRA STRENGTH

docusate sodium capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:17856-0443(NDC:24385-443)
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 RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color	ORANGE	**Score**	no score
Shape	CAPSULE	**Size**	20mm
Flavor		**Imprint Code**	P20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-0443-1	1 in 1 POUCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	07/09/2010	

Labeler - Atlantic Biologicals Corps (047437707)

Registrant - Atlantic Biologicals Corps (047437707)

Establishment

Name	Address	ID/FEI	Business Operations
Atlantic Biologicals Corps		047437707	RELABEL(17856-0443) , REPACK(17856-0443)

Revised: 11/2012 Atlantic Biologicals Corps