STOOL SOFTENER LAXATIVE- docusate sodium capsule, liquid filled
ATLANTIC BIOLOGICALS CORP.

Drug Facts

Active ingredient (in each softgel)

Docusate sodium 250 mg

Purpose

Stool softener laxative

Uses

- relieves occasional constipation (irregularity)
- 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 last 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 13 mg
- store between 20-25ºC(68-77ºF); excursions permitted between 15-30ºC (59-86ºF)

Inactive Ingredients

anhydrous citric acid, FD&C red #40, FD&C yellow #6, gelatin, glycerin, isopropyl alcohol, lecithin, mannitol, mineral oil, polyethylene glycol, propylene glycol, purified water, sorbitan, sorbitol, white ink

Questions?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

Extra Strength

Docusate Sodium

250 mg

Stool Softener Laxative

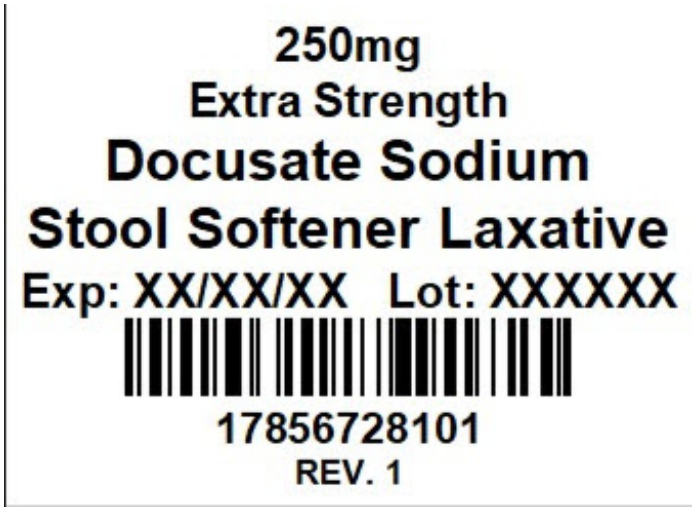
Softgels

Distributed by:

ATLANTIC BIOLOGICALS CORP.

MIAMI, FL 33179

Product Label



STOOL SOFTENER LAXATIVE

docusate sodium capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:17856-7281(NDC:0904-7281)
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 GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MANNITOL (UNII: 3OWL53L36A)	
MINERAL OIL (UNII: T5L8T28FGP)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics			
Color	orange (Clear)	**Score**	no score
Shape	CAPSULE	**Size**	20mm
Flavor		**Imprint Code**	P4
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:17856-7281-1	100 in 1 BOX, UNIT-DOSE	02/20/2024	
1	NDC:17856-7281-2	1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M	10/14/2022	

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment

Name	Address	ID/FEI	Business Operations
UNIT DOSE SOLUTIONS		360804194	repack(17856-7281)

Revised: 2/2024 ATLANTIC BIOLOGICALS CORP.