SILACE- docusate sodium liquid
ATLANTIC BIOLOGICALS CORP.

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.

Silace Liquid

Active Ingredient: Docusate sodium 10 mg (in each 1 mL)

Purpose: Stool Softener

Uses

- for gentle, reliable relief from occasional constipation (irregularity)
- generally produces bowel movement in 12 to 72 hours

Warning

- **Do not use** laxative products for longer than 1 week unless told to do so by a doctor
- if you are presently taking mineral oil unless told to do by a doctor

Ask doctor before use if you have

- stomach pain
- nausea
- vomiting
- noticed a sudden change in bowel habits that last over two 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

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 as indicated by doctor
- this product must be given in a 6 to 8 oz. glass of milk or fruit juice or infant's formula to prevent throat irritation. Dose may be taken as a single daily dose or in divided doses
- dosage should be adjusted to individual response
- higher doses are recommended for initial therapy
- the effect on stools is usually apparent 1 to 3 days after the first dose

Adults and children over 12 years	50 to 200 mg (1 to 4 teaspoonful)
Children 6 to under 12 years	50 to 100 mg (1 to 2 teaspoonful)
Children 3 to under 6 years	25 to 50 mg(1/2 to 1 teaspoonful)
Children under 3 years of age	Ask a doctor

Other information

- store at room temperature 20°-25°C (68°-77°F)
- protect from freezing and excessive heat

- do not use if tamperevident safety seal around cap is broken or missing
- dispense in tight, light-resistant container with a child-resistant closure

Inactive ingredients

citric acid, D&C red no. 33, flavor, methylparaben, Poloxamer, propylene glycol, propylparaben, purified water, sodium citrate.

Questions

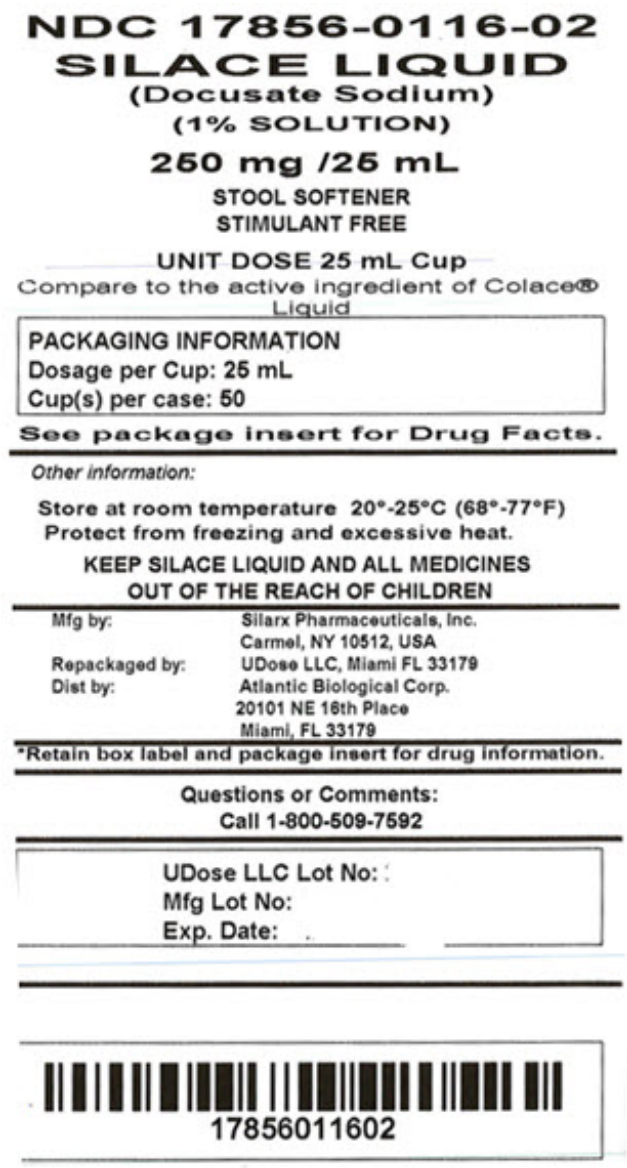
888-974-5279

This product is not manufactured or distributed by Purdue Products LP, distributor of Colace® Liquid.

Manufactured by:

Silarx Pharmaceuticals, Inc.
1033 Stoneleigh Ave
Carmel, NY 10512
USA

17856-0116-02



SILACE

docusate sodium liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:17856-0116(NDC:54838-116)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Docusate sodium (UNII: F05Q2T2JA0) (Docusate - UNII:M7P27195AG)	Docusate sodium	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
anhydrous citric acid (UNII: XF417D3PSL)	
D&C red no. 33 (UNII: 9DBA0SBB0L)	
methylparaben (UNII: A2I8C7HI9T)	
propylene glycol (UNII: 6DC9Q167V3)	
propylparaben (UNII: Z8IX2SC1OH)	
sodium citrate (UNII: 1Q73Q2JULR)	
water (UNII: 059QF0KO0R)	
Poloxamer 407 (UNII: TUF2IVW3M2)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	LEMON (Lemon Vanilla Flavor)	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:17856-0116-2	25 mL in 1 CUP; Type 0: Not a Combination Product	10/07/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	10/05/1990	

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment

Name	Address	ID/FEI	Business Operations

ATLANTIC BIOLOGICALS CORP.		047437707	repack(17856-0116) , relabel(17856-0116)

Revised: 10/2016 ATLANTIC BIOLOGICALS CORP.