

**SILACE- docusate sodium syrup**  
**Lannett Company, Inc.**

*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.*

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**Silace syrup**

Active Ingredient: Docusate sodium 60 mg (in each 15 mL (1 tablespoonful))

Purpose: Stool Softener

**Uses**

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

**Warnings**

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

- doses must be given in a 6-8 oz glass of milk or fruit juice, to prevent throat irritation
- dose may be taken as a single daily dose or in divided doses
- dosage should be adjusted to individual response

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Adults and children 12 years of age and older	1 to 6 tablespoonfuls, or as directed by a doctor
Children 6 to under 12 years of age	1 to 2 1/2 tablespoonfuls, or as directed by a doctor
Children under 6 years	Ask a doctor

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#### **Other information**

- **store at room temperature 20°-25°C (68°-77°F)**
- **protect from freezing and excessive heat**
- **do not use if tamper-evident safety seal around cap is broken or missing**
- **dispense in tight, light-resistant container with a child-resistant closure**

#### **Inactive ingredients:**

alcohol not more than 1%, citric acid, D&C red no. 33, FD&C red no. 40, peppermint flavor, glycerin, methylparaben, propylene glycol, propylparaben, purified water, sodium benzoate, sodium citrate, sucrose.

#### **Questions**

**888-974-5279**

Manufactured by:

Silarx Pharmaceutical, Inc.

1033 Stoneleigh Ave

Carmel , NY 10512-USA.

**Drug Facts**

**Active ingredient (in each 15 mL (1 tablespoonful)) Purpose**  
Docusate sodium 60 mg ..... Stool softener

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

**Warnings** - Do not use laxative products for longer than 1 week unless told to do so by a doctor - 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 last over two weeks

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**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.

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354838-107-807

10-1083  
Rev. 04/18

**Questions** ☎ 1-844-834-0530



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

**SILARX**

NDC 54838-107-80

# SILACE SYRUP

**Contains Alcohol  
not more than 1%**

**Stool Softener  
Stimulant Free**

**BULK CONTAINER – NOT  
FOR HOUSEHOLD USE**

This container is not child-resistant.  
Pharmacist - Dispense in a tight, light-resistant container with child-resistant closure.

† Compare to the active ingredient of Colace® Syrup

**TAMPER EVIDENT: Do not use  
if tamper-evident safety seal  
around cap is broken or missing**

**473 mL (1 Pint)**

Manufactured by:  
Silarx Pharmaceuticals, Inc.  
1033 Stoneligh Ave., Carmel, NY 10612

## SILACE

docusate sodium syrup

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54838-107
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	60 mg in 15 mL

### Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCROSE (UNII: C151H8M554)	

### Product Characteristics

Color		Score	
Shape		Size	
Flavor	PEPPERMINT (peppermint Flavor)	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54838-107-80	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/05/1990	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	03/05/1990	

**Labeler** - Lannett Company, Inc. (161630033)

Revised: 8/2018

Lannett Company, Inc.