SILACE - docusate sodium syrup
Silarx Pharmaceuticals,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.

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

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

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.

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		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	03/05/1990	

Labeler - Silarx Pharmaceuticals,Inc (161630033)

Revised: 6/2014 Silarx Pharmaceuticals,Inc