ONELAX- docusate sodium liquid
Akron Pharma

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.

OneLAX
Docusate Sodium Liquid
50 mg/5 mL

Drug Facts

Active ingredient (in each 5 mL)

Docusate Sodium 50 mg

Purpose

Stool Softner Laxative

Uses

- relieves occasional constipation (irregularity)
- generally produces bowel movement in 12 to 72 hours

Warnings

Do Not Use for more than one week unless directed by a doctor.

Ask a doctor before use if you

- have stomach pain, nausea or vomiting
- have sudden change in bowel habits that persists over a period of 2 weeks
- are presently taking mineral oil

Stop use and ask a doctor if

- you have rectal bleeding or fail to have a bowel movement after use of this product. These could be signs of a serious condition.
- a skin rash occurs
- you experience throat irritation

if pregnant or breast-feeding,

ask doctor before use.

Keep out of reach of children

In case of accidental overdose, seek medical assistance or contact a Poison Control Center right away.

Directions

- shake well before using
- follow dosing directions below or use as directed by a physician
- do not exceed recommended dose
- must be given in a 6 oz to 8 oz glass of milk or fruiit juice to prevent throat irritation
- take maximum dose daily until first bowel movement, dosage should then be reduced according to indivisual response

Age	Dose
Adults and children over 12 years of age and over	1 to 6 teaspoons (5 mL - 30 mL)
Children under 12 years of age	Ask a doctor

Other information

- wach teaspoonful (5 ml) contains: sodium 5 mg
- store at room temperature 15º - 30ºC (59º - 86ºF)
- protect from excessive heat
- Pharmacist-preserve and dispense in a tight, light resistant container with a child resistant cap as defined in the USP
- Temper -Evident: Do not use if foil over bottle opening is torn, broken, or missing

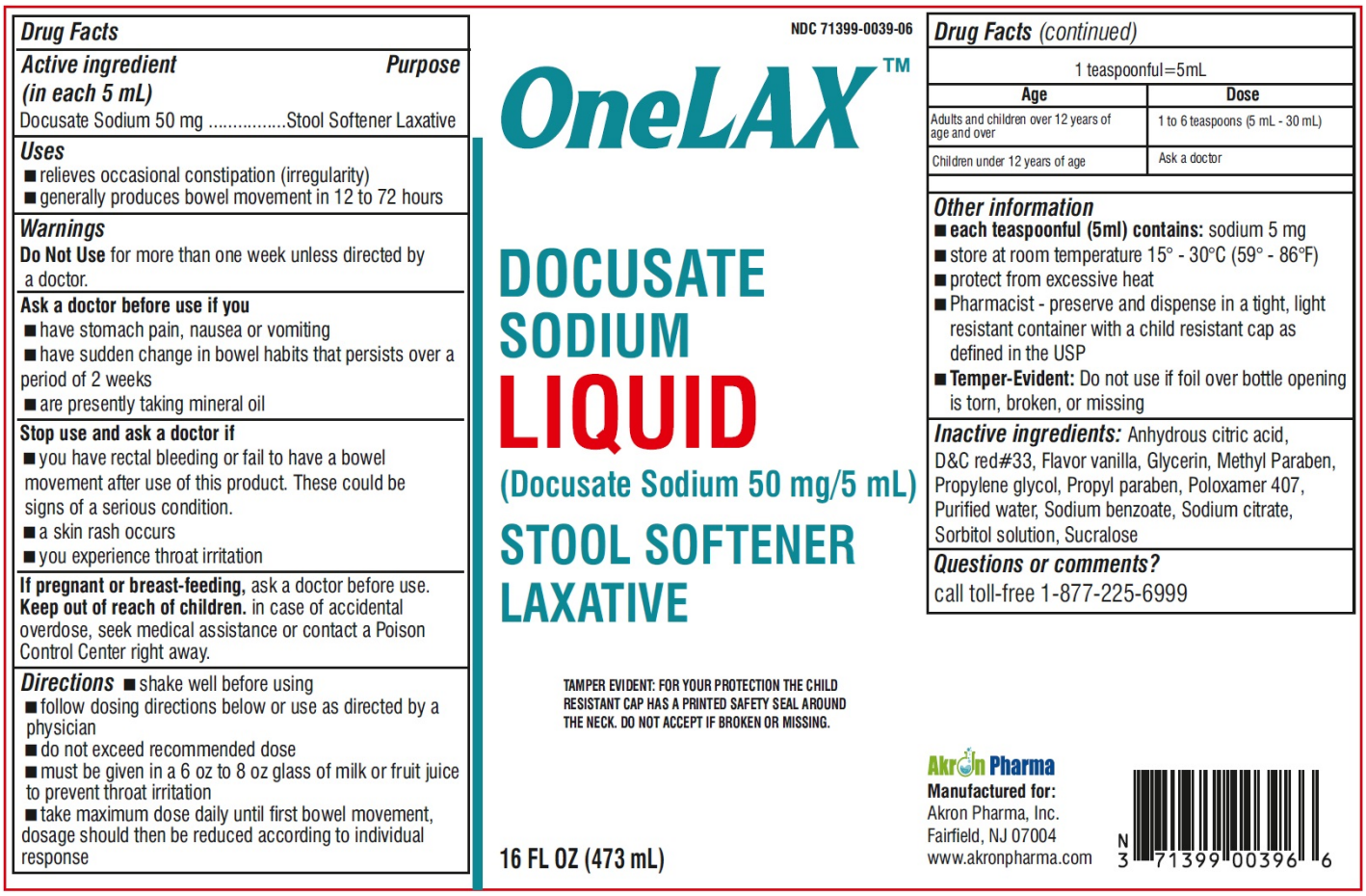
Inactive ingredients:

Anhydrous citric acid, D&C red#33, Flavor vanilla, Glycerin, Methyl Paraben, Propylene glycol, Propyl paraben, Poloxamer 407, Purified water, Sodium benzoate, Sodium citrate, Sorbitol solution, Sucralose

Questions or comments?

call toll-free 1-877-225-6999

Manufactured for:
Akron Pharma, Inc.
Fairfield, NJ 07004
www.akronpharma.com



ONELAX

docusate sodium liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71399-0039
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
WATER (UNII: 059QF0KO0R)	

SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71399-0039-6	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/04/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	08/04/2023	

Labeler - Akron Pharma (067878881)

Revised: 8/2023 Akron Pharma