STOOL SOFTENER- docusate sodium capsule, liquid filled
Mckesson (Sunmark)

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.

Drug Facts

Active Ingredient (in each softgel)

Docusate Sodium 100 mg

Purpose

Stool softener

Uses

- for the prevention of dry, hard stools
- for relief of occasional constipation. This product generally produces a bowel movement within 12 to 72 hours.

Warnings - Do not use

- if you are currently taking mineral oil, unless directed by a doctor
- when abdominal pain, nausea or vomiting are present
- for longer than one week, unless directed by a doctor

Ask a doctor before use if

you notice a sudden change in bowel habits that persists over a period of 2 weeks

Stop use and ask a doctor if

- you have rectal bleeding
- you fail to have a bowel movement after use

If pregnant or breastfeeding

ask a health care 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

- **adults and children 12 years and over:** take 1- 2 softgels preferably at bedtime
- **children 6 to 12 years of age:** take 1 softgel at bedtime

Other information

- **each softgel contains:** sodium 6mg
- store at controlled room temperature 15º - 30º C (59º- 86º F)
- do not use if imprinted safety seal under cap is broken or missing.
- *This product is not manufactured or distributed by Purdue Pharma L.P., owner of the registered trademark Colace®

Inactive Ingredients

edible ink, D&C Red #33, FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, sorbitol special and titanium dioxide. May also contain: FD&C blue #1 and purified water.

Principal Display Panel

Compare to COLACE® active ingredient*

stool softener

Relief of occasional constipation

Docusate sodium 100 mg

Another quality product distributed by McKesson

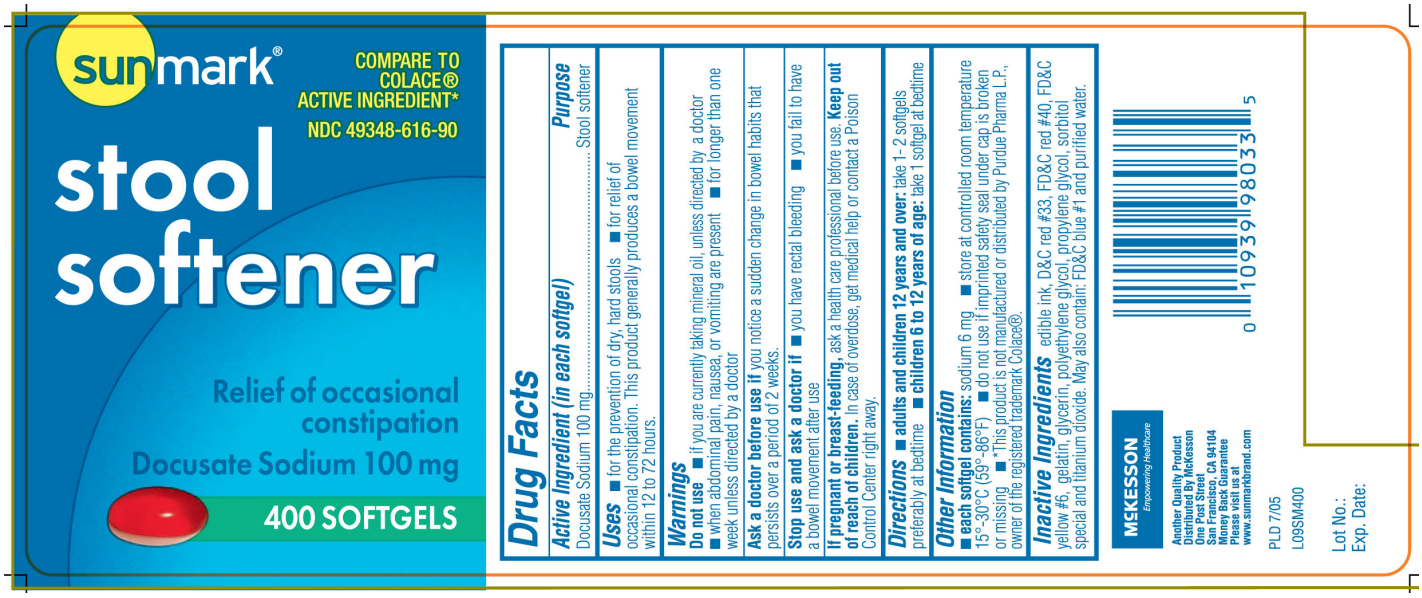
one post street

San Francisco, CA 94104

Money back gurantee

Please visit us at www.sunmarkbrand.com

Product Label



Docusate Sodium 100 mg

STOOL SOFTENER

docusate sodium capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:49348-616
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (DOCUSATE)	DOCUSATE SODIUM	100 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40	
FD&C YELLOW NO. 6	
GELATIN	
GLYCERIN	
POLYETHYLENE GLYCOLS	
PROPYLENE GLYCOL	
SORBITOL	
D&C RED NO. 33	
TITANIUM DIOXIDE	
FD&C BLUE NO. 1	
WATER	

Product Characteristics

Color	RED, WHITE	**Score**	no score
Shape	OVAL	**Size**	13mm
Flavor		**Imprint Code**	P10;51A
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49348-616-10	1 in 1 BOX		
1		100 in 1 BOTTLE		
2	NDC:49348-616-90	400 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	07/09/2010	

Labeler - Mckesson (Sunmark) (177667227)

Revised: 9/2012 Mckesson (Sunmark)