STOOL SOFTENER- docusate sodium capsule, liquid filled Walgreen Co.

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.

Stool Softener

Drug Facts

Active ingredient (in each softgel)

Docusate sodium 100 mg

Purpose

Stool softener laxative

Uses

- for relief of occasional constipation (irregularity)
- this product generally produces a bowel movement in 12 to 72 hours

Warnings

Ask a doctor before use if you have

- stomach pain, nausea, or vomiting
- a sudden change in bowel habits that lasts over 14 days

Ask a doctor or pharmacist before use if you are Opresently taking mineral oil

Stop use and ask a doctor if

- you have rectal bleeding or no bowel movement after using this product. These could be signs of a serious condition.
- you need to use a laxative for more than 1 week

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 softgels with a full glass (8oz) of water

adults and children 12	take 1 to 3 softgels daily or as directed by a doctor. This dose may be taken		
years and older	as a single daily dose or in divided doses.		
children 6 to under 12	take 1 softgel daily or as directed by a doctor		
years			
children under 6 years	ask a doctor		

Other information

- each softgel contains: sodium 5 mg
- store at room temperature 15°-30°C (59°-86°F)
- protect from excessive humidity

Inactive ingredients

anhydrous citric acid, FD&C red # 40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water, sorbitol sorbitan solution and white edible ink

Questions or comments?

Call toll free: 1-855-215-8180

PRINCIPAL DISPLAY PANEL - Carton

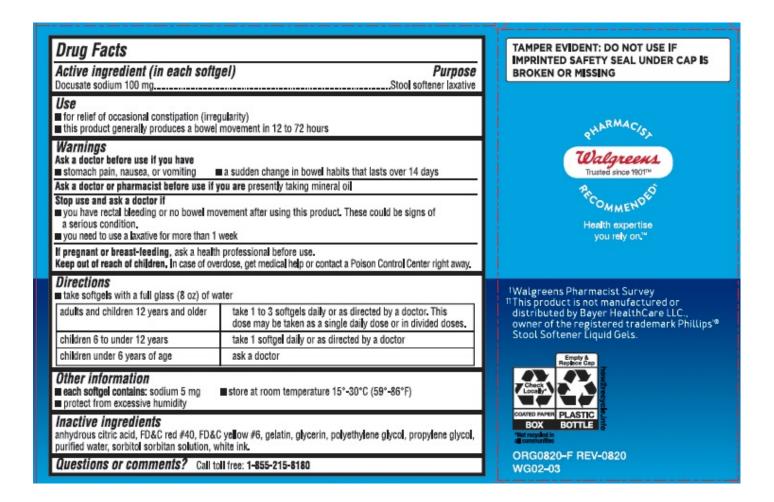
Stool Softener

DOCUSATE SODIUM 100 mg 30 SOFTGELS

Compare to Phillips' Stool Softener Liquid Gels active ingredient

NDC 0363-9944-20





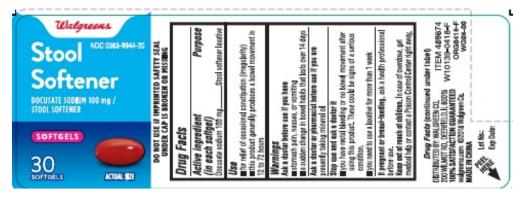
PRINCIPAL DISPLAY PANEL - Bottle

Stool Softener

DOCUSATE SODIUM 100 mg 30 SOFTGELS

Compare to Phillips' Stool Softener Liquid Gels active ingredient

NDC 0363-9944-20



STOOL SOFTENER

docusate sodium capsule, liquid filled

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-9944	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	100 mg	

Inactive Ingredients				
Ingredient Name	Strength			
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
GELATIN (UNII: 2G86QN327L)				
GLYCERIN (UNII: PDC6A3C0OX)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SORBITOL (UNII: 506T60A25R)				
SORBITAN (UNII: 6 O 9 2 I C V 9 R U)				

Product Characteristics			
Color	red (clear)	Score	no score
Shape	capsule (oval)	Size	13mm
Flavor		Imprint Code	PC1
Contains			

1	Packaging			
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-9944-20	1 in 1 CARTON	03/29/2018	

1 3	0 in 1 BOTTLE; Type 0: Not a Combination Product			
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part334	03/29/2018		

Labeler - Walgreen Co. (008965063)

Establishment				
Name	Address	ID/FEI	Business Operations	
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(0363-9944), analysis(0363-9944)	

Revised: 12/2020 Walgreen Co.