DOCUSATE CALCIUM- docusate calcium capsule Rebel Distributors Corp

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.

Docus ate Calcium

Active ingredient(s)

Docusate Calcium

Purpose

Stool Softener

Use(s)

for relief of occasional constipation. This product generally produces a bowel movement within 12 to 72 hours.

Warnings

Do not use

- -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 1 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.

Ask a doctor or pharmacist 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

Pregnancy/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 over 12 years of age: take 1 softgel daily for several days, or until bowel movements are normal, or as directed by a doctor

-children under 12 years of age: take as directed by a doctor

Other information

- -do not use if imprinted safety seal under cap is broken or missing
- -This product is not manufactured or distributed by Chattem, Inc., owner of the registered trademark Surfak Stool Softener

Storage

Store at controlled room temperature 15 degrees-30 degrees C (59 degrees-86 degrees F)

Inactive ingredients

Corn oil, D&C Red #33, FD&C Red #40, gelatin, glycerin, purified water and sorbitol special.

Questions

Adverse Drug Event Call: (800) 616-2471

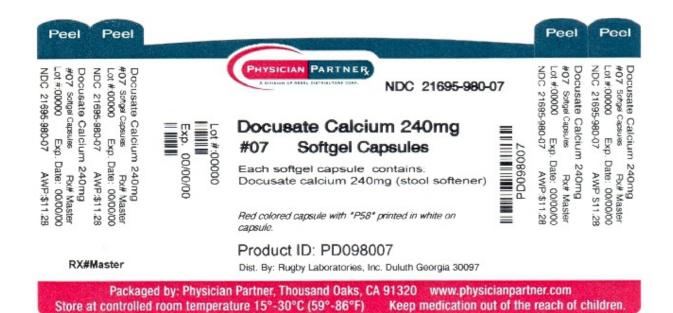
Distributed by: Rugby Laboratories, Inc. Duluth GA 30097

Repackaged by: Rebel Distributors Corp Thousand Oaks, CA 91320

Principal Display Panel

Docusate Calcium Softgel Capsules

240mg



DOCUSATE CALCIUM

docusate calcium capsule

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21695-980(NDC:0536-3755)	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DO CUSATE CALCIUM (UNII: 6K7YS503HC) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE CALCIUM	240 mg	

Inactive Ingredients			
Strength			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
GELATIN (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6 A3C0 OX)			

SORBITOL (UNII: 506T60A25R)

Product Characteristics				
Color	RED	Score	no score	
Shape	CAPSULE	Size	21mm	
Flavor		Imprint Code	P58	
Contains				

Pa	nckaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21695-980-07	07 in 1 BOTTLE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part334	07/01/2010		

Labeler - Rebel Distributors Corp (118802834)

Establishment				
Name	Address	ID/FEI	Business Operations	
Rebel Distributors Corp		118802834	RELABEL, REPACK	

Revised: 9/2011 Rebel Distributors Corp