DOCUSATE SODIUM- docusate sodium 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.

Docusate Sodium Drug Facts

Active ingredient

Docusate Sodium 100mg

Purpose

Stool Softener

Keep Out of Reach of Children

In case of overdose, get medical help or contact a Poison Control center right way.

Uses

Prevents / relieves dry hard stool. Results usually occur 1 to 3 days after the first dose.

Warnings

Do not use for more than one week unless directed by a doctor.

Ask a doctor before use if you have abdominal pain, nausea, or vomiting; have noticed a sudden change in bowel habits that lasts over 2 weeks,; are taking mineral oil.

Stop use and ask a doctor if you have no bowel movement within 3 days; you have rectal bleeding. **These could be signs of a serious condition.**

If pregnant or breast-feeding, ask a health professional before use.

Tamper Evident: Do not use if imprinted seal under cap is missing or broken.

Directions

Adults and children 12 years and older: take 1-2 softgels daily until first bowel movement; 1 softgel daily thereafter, or as directed by a doctor.

Children under 12: consult a doctor.

Do not exceed recommended dose.

Other Information

Each softgel contains sodium 5mg.

Product from Canada or USA

Store at room temperature, 15°C-30°C (59°F-86°F)

Inactive ingredients

may contain cirtic acid, D&C red no. 33, D&C yellow no. 10, ethyl vanillin, FD&C blue no. 1, FD&C re no. 40 FD&C yellow no. 6, gelatin, glycerin, edible ink, mannitol, methylparaben, polyethylene glycol, propylene glycol, propylparaben, sorbitol, water.

Distributed by:

Geri-Care Pharmaceuticals Corp.

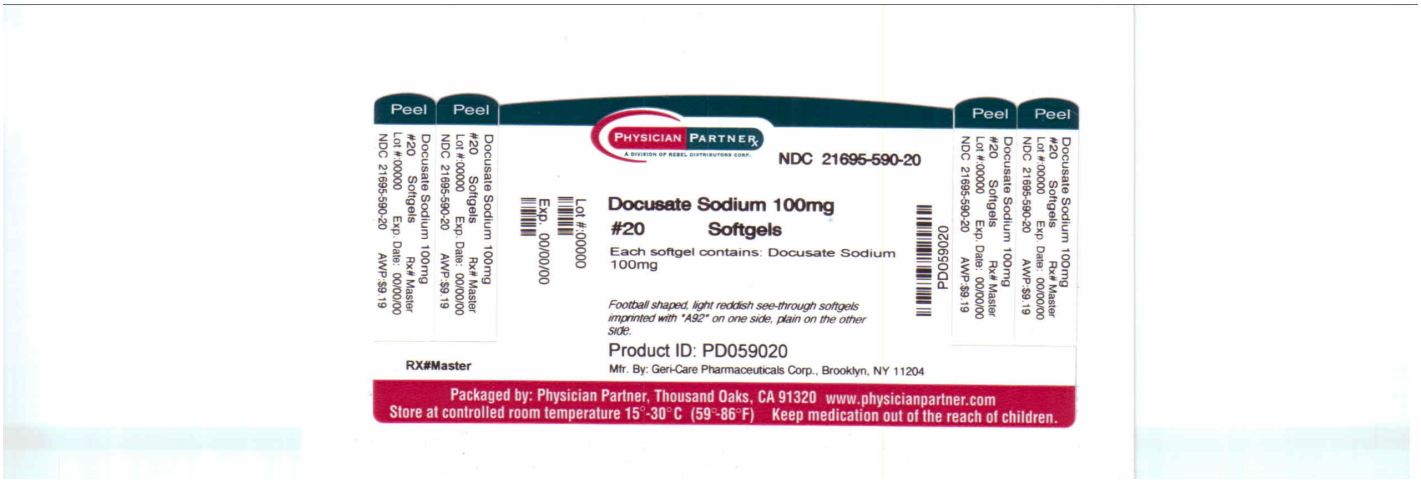
Brooklyn, NY 11204

Repackaged by:

Rebel Distributors Corp

Thousand Oaks, CA 91320

Package/Label Principal Display Panel



DOCUSATE SODIUM

docusate sodium capsule

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:21695-590(NDC:57896-401)
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**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
ETHYL VANILLIN (UNII: YC9ST449YJ)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
MANNITOL (UNII: 3OWL53L36A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	RED	**Score**	no score
Shape	OVAL	**Size**	14mm
Flavor		**Imprint Code**	A92
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21695-590-20	20 in 1 BOTTLE		
2	NDC:21695-590-30	30 in 1 BOTTLE		
3	NDC:21695-590-90	90 in 1 BOTTLE		
4	NDC:21695-590-00	100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	01/01/2007	

Labeler - Rebel Distributors Corp (118802834)

Establishment

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

Revised: 2/2011 Rebel Distributors Corp