DOCUSATE SODIUM- docusate sodium capsule, liquid filled
NCS HealthCare of KY, Inc dba Vangard Labs

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 100mg

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 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

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 over 12 years of age:** take 1 to 3 softgels preferably at bedtime
- **children 6- 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)
- *This product is not manufactured or distributed by Purdue Pharma L.P., owner of the registered trademark Colace®

Inactive Ingredients

edible ink, FDandC Red #40, FDandC Yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water and sorbitol special.

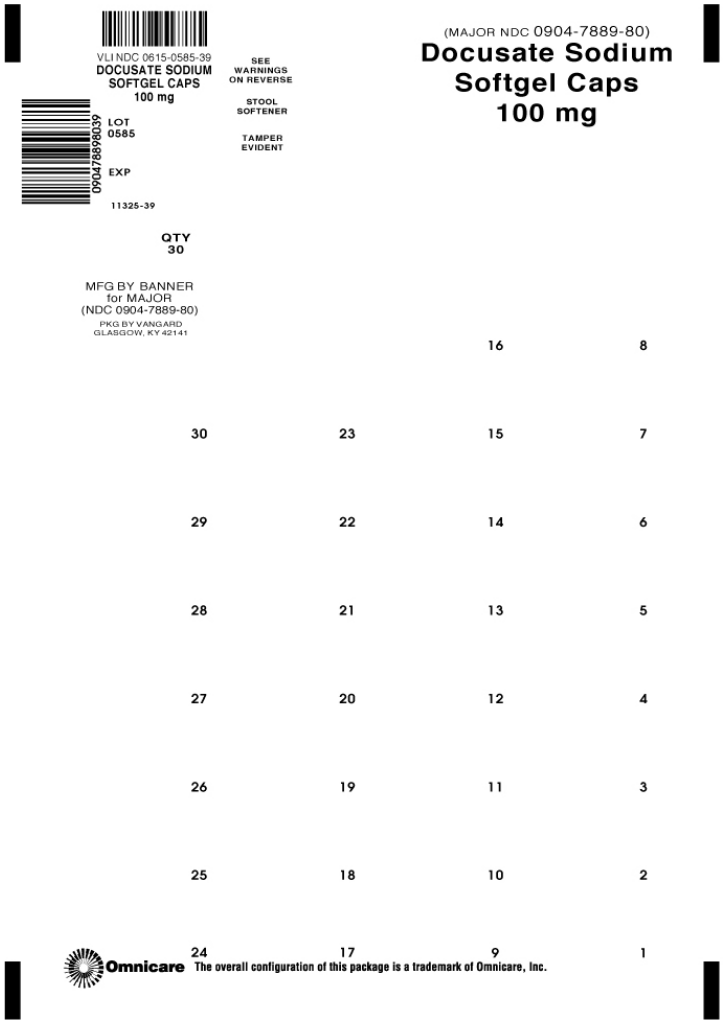
Questions or comments?

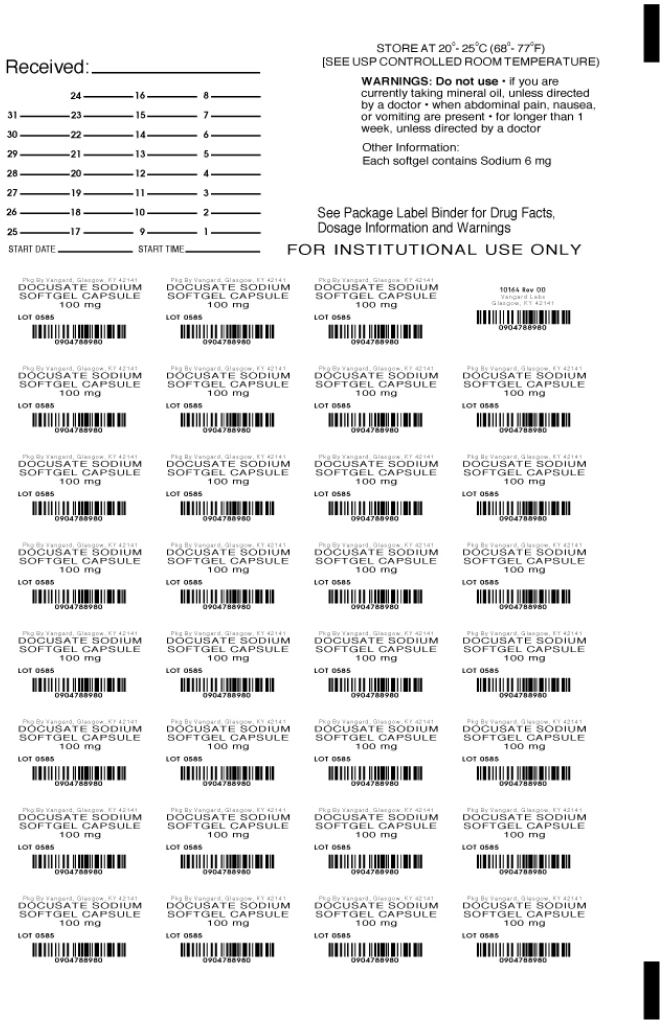
Adverse Drug Event Call: **(800)-616-2471)**

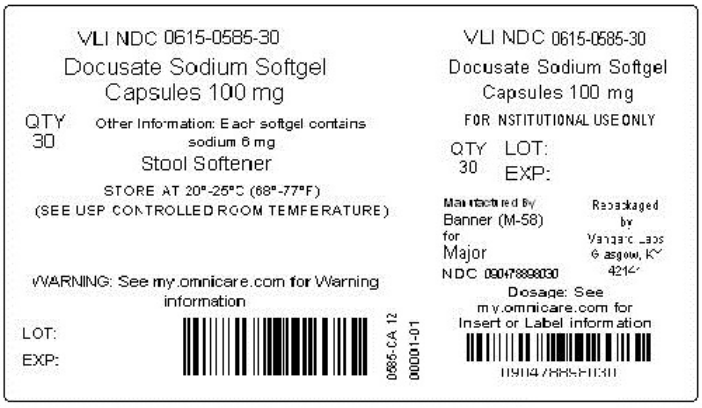
Distributed by : Major Pharmaceuticals, 31778 Enterprise Drive, Livonia, MI 48150, U.S.A.

Rev. 2/09

Principal Display Panel







DOCUSATE SODIUM

docusate sodium capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0615-0585(NDC:0904-7889)
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**
FD&C RED NO. 40 (UNII: WZB9127XOA)	

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

Product Characteristics

Color	ORANGE (ORANGE)	**Score**	no score
Shape	OVAL (OVAL)	**Size**	13mm
Flavor		**Imprint Code**	P51
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0615-0585-30	6 in 1 BOX, UNIT-DOSE		
1		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0615-0585-05	15 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0615-0585-31	31 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:0615-0585-39	30 in 1 BLISTER PACK; 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	04/23/2010	

Labeler - NCS HealthCare of KY, Inc dba Vangard Labs (050052943)

Establishment

Name	Address	ID/FEI	Business Operations
NCS HealthCare of KY, Inc dba Vangard Labs		050052943	REPACK(0615-0585)

Revised: 1/2015 NCS HealthCare of KY, Inc dba Vangard Labs