DOCUSATE SODIUM- docusate sodium capsule
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.

Docusate Sodium 250mg

Active ingredient (in each softgel)

Docusate Sodium 250mg

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 more 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 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 and over:** take 1 softgel daily or as directed by a doctor

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

Other information

- **each softgel contains:** sodium 15mg
- store at controlled room temperature 15° - 30° C (59° - 86° F)
- do not use if imprinted safety seal under cap is broken or missing

Inactive ingredients

edible white ink, FD&C Red # 40, FD&C Yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water, sorbitol special.

Questions?

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

Distributed by:

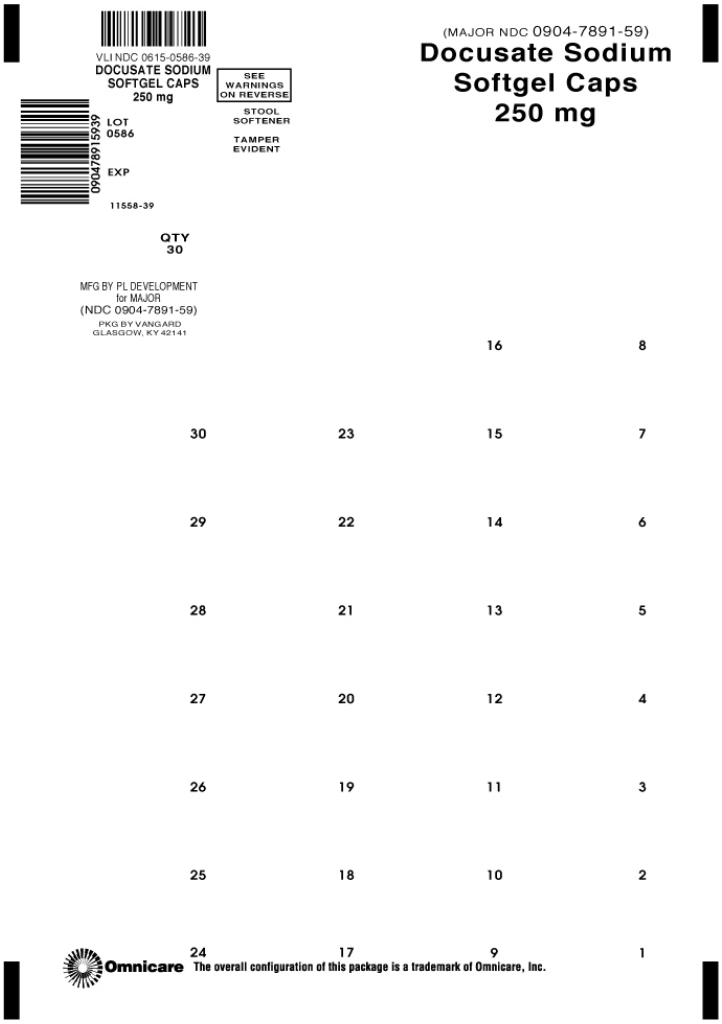
Major Pharmaceuticals

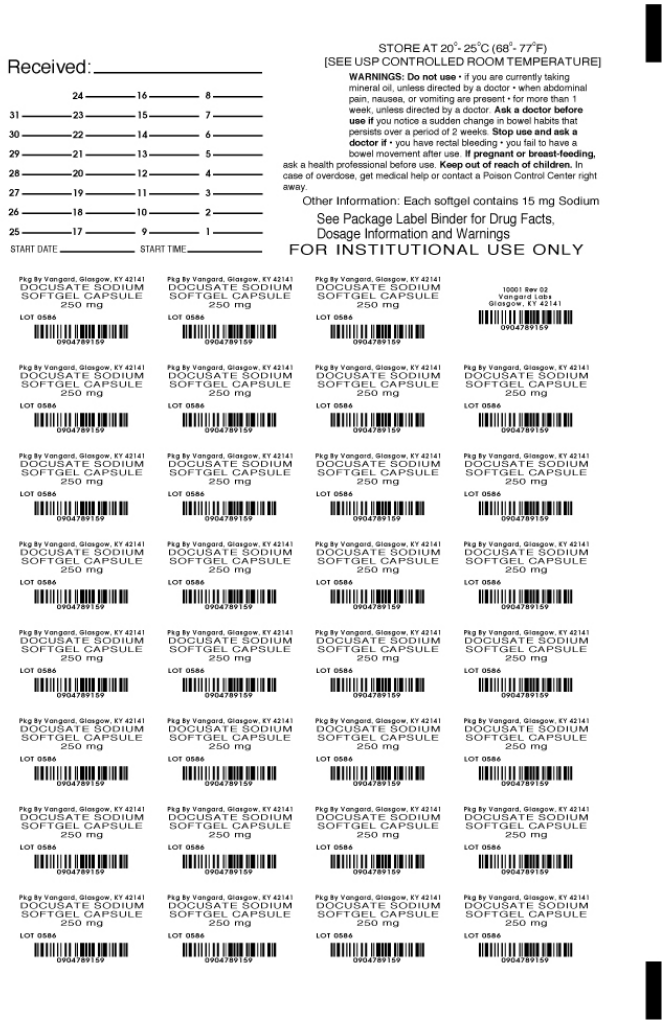
31778 Enterprise Drive

Livonia, MI 48150, USA

Principal Display Panel

Docusate Sodium Softgel Caps 250mg





DOCUSATE SODIUM

docusate sodium capsule

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0615-0586(NDC:0904-7891)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	250 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)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	

Product Characteristics			
Color	RED (Orange)	**Score**	no score
Shape	CAPSULE	**Size**	21mm
Flavor		**Imprint Code**	P20
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0615-0586-39	30 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	07/01/2010	

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	RELABEL(0615-0586) , REPACK(0615-0586)