STOOL SOFTENER LAXATIVE- docusate sodium capsule, liquid filled NCS HealthCare of KY, LLC dba Vangard Labs

DRUG FACTS

Active ingredient (in each softgel)

Docusate sodium 100 mg

Purpose

Stool softener laxative

Uses

- relieves occasional constipation (irregularity)
- generally produces bowel movement in 12 to 72 hours

Warnings

Do not use

if you are presently taking mineral oil, unless told to do so by a doctor.

Ask a doctor before use if you have

- stomach pain
- nausea
- vomiting
- noticed a sudden change in bowel habits that lasts over 2 weeks

Stop use and ask a doctor if

- you have rectal bleeding or fail to have a bowel movement after use of a laxative. These could be signs of a serious condition.
- you need to use a stool softener laxative for more than 1 week

If pregnant or breast-feeding,

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 (1-800-222-1222) right away.

Directions

• take only by mouth. Doses may be taken as a single daily dose or in divided doses.

adults and children 12 years and over	take 1-3 softgels daily
children 2 to under 12 years of age	take 1 softgel daily
children under 2 years	ask a doctor

Other information

- each softgel contains: sodium 7 mg
- store at 25°C (77°F); excursion permitted between 15-30°C (59-86°F)

Inactive ingredients

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

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

compare to the active ingredient in Colace® Regular Strength Stool Softener† docusate sodium

docusate sodium 100 mg

stool softener laxative

- gentle
- dependable
- stimulant-free

softgels

[†]This product is not manufactured or distributed by Avrio Health L.P., distributor of Colace[®] Regular Strength Stool Softener.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

Distributed by:

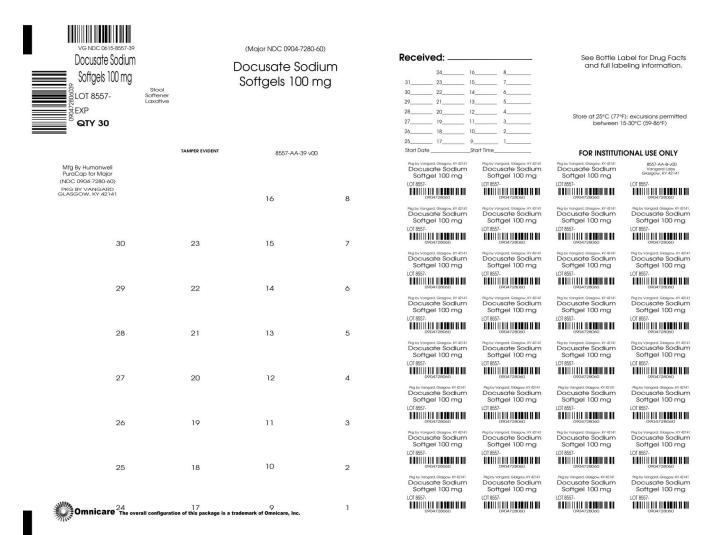
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PRINCIPAL DISPALY PANEL - BINGO CARD



PRINCIPAL DISPALY PANEL - UNIT DOSE



Docusate Sodium Softgel 100 mg

Pkg By Vangard, Glasgow, KY 42141
Docusate Sodium
Softgel 100 mg
LOT 8557-

Pkg By Vangard, Glasgow, KY 42141 Docusate Sodium Softgel 100 mg

Pkg By Vongard, Glasgow, KY 42141 Docusate Sodium Softgel 100 mg

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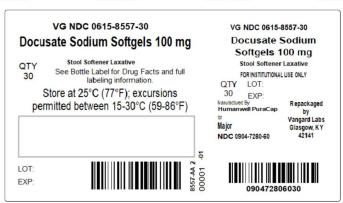
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STOOL SOFTENER LAXATIVE

docusate sodium capsule, liquid filled

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0615-8557(NDC:0904-7280)

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			
In	gredient Name	Strength	
FD&C RED NO. 40 (UNII: WZB9127XOA)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8	3)		
GELATIN (UNII: 2G86QN327L)			

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics			
Color	red	Score	no score
Shape	CAPSULE (Oval)	Size	13mm
Flavor		Imprint Code	PC1
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0615- 8557-39	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	12/11/2024	
2	NDC:0615- 8557-30	6 in 1 BOX, UNIT-DOSE	01/09/2025	
2		5 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 Drug	M007	11/15/2022	

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

Establishment				
Name	Address	ID/FEI	Business Operations	
NCS HealthCare of KY, LLC dba Vangard Labs		050052943	repack(0615-8557)	

Revised: 1/2025 NCS HealthCare of KY, LLC dba Vangard Labs