

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

MAJOR[®] PHARMACEUTICALS

Indianapolis, IN 46268

(800) 616-2471

www.majorpharmaceuticals.com

PRINCIPAL DISPLAY PANEL - BINGO CARD



VG NDC 0615-8557-39

Docosate Sodium Softgels 100 mg

LOT 8557-

EXP

QTY 30

Stool Softener Laxative

(Major NDC: 0904-7280-60)

Docosate Sodium Softgels 100 mg

TAMPER EVIDENT

8557-AA-39 v00

Mfg By Humanwell PuraCap for Major (NDC 0904-7280-60) PKG BY VANGARD GLASGOW, KY 42141

			16	8
30	23	15	7	
29	22	14	6	
28	21	13	5	
27	20	12	4	
26	19	11	3	
25	18	10	2	
24	17	9	1	



The overall configuration of this package is a trademark of Omnicare, Inc.

Received:

24	16	8
31	23	15
30	22	14
29	21	13
28	20	12
27	19	11
26	18	10
25	17	9
Start Date	Start Time	

See Bottle Label for Drug Facts and full labeling information.

Store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F)

FOR INSTITUTIONAL USE ONLY

Pkg by Vanguard, Glasgow, KY 42141 Docosate Sodium Softgel 100 mg LOT 8557- 	Pkg by Vanguard, Glasgow, KY 42141 Docosate Sodium Softgel 100 mg LOT 8557- 	Pkg by Vanguard, Glasgow, KY 42141 Docosate Sodium Softgel 100 mg LOT 8557- 	8557-AA-B-00 Vanguard Labs Glasgow, KY 42141 LOT 8557-
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PRINCIPAL DISPLAY PANEL - UNIT DOSE

8557-AA-UDI-V00

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VG NDC 0615-8557-30 Docosate Sodium Softgels 100 mg Stool Softener Laxative QTY 30 See Bottle Label for Drug Facts and full labeling information. Store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F)		VG NDC 0615-8557-30 Docosate Sodium Softgels 100 mg Stool Softener Laxative FOR INSTITUTIONAL USE ONLY QTY 30 LOT: EXP: Manufactured By Humanwell PuraCap or Major NDC 0904-7280-60	
LOT: EXP:		Repackaged by Vanguard Labs Glasgow, KY 42141	
 8557-AA 2 00001 -01		 090472806030	

STOOL SOFTENER LAXATIVE

docosate 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

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
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	11/30/2025
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 Vanguard Labs (050052943)

Establishment

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

Revised: 1/2025

NCS HealthCare of KY, LLC dba Vanguard Labs